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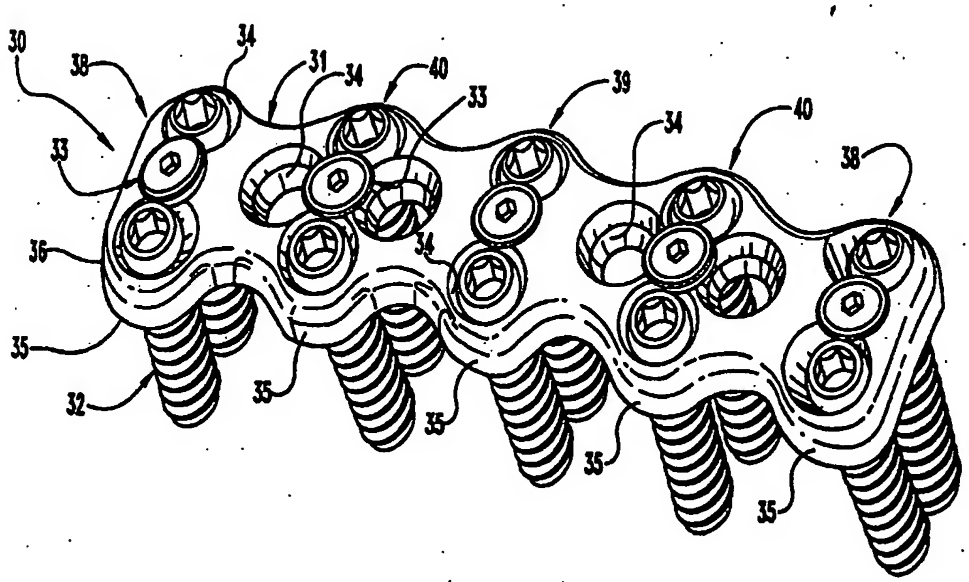

(57) Abstract

In one embodiment of the invention, an anterior fixation system (30) includes a plate (31a–31g) defining a plurality of screw holes (34), a number of screws (32) and a number of locking assemblies (33) for fixing the screws (32) to the plate (31a–31g). The system (30) includes two bone screws (32), a fixed angle screw (50) and a variable angle screw (60). Either the fixed or variable angled screws (50, 60) may be implanted with a single plate (31a–31g), and either type of screw (50, 60) may be placed into any of the screw holes (34) along the plate (31a–31g). The several screw holes (34) may be in various patterns (38, 39, 40, 41, 42, 43, 44). The invention further contemplates a locking assembly (33) to lock one or more bone screws (32) within a respective screw hole (34). In one embodiment, the locking assembly (33) includes a washer (90) overlapping one or more screw holes (34), and a locking screw (85). In another embodiment, a locking washer (120) includes cut-outs (128) corresponding to the screw recesses (105), along with a notch (110) and key (129) configuration.

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ANTERIOR CERVICAL PLATING SYSTEM

BACKGROUND OF THE INVENTION

The present invention concerns spinal instrumentation systems, most particularly for use in fixation of the cervical spine. More particularly, the invention pertains to a plating system for use in the treatment of various spinal pathologies.

As with any bony structure, the spine is subject to various pathologies that compromise its load bearing and support capabilities. The spine is subject to degenerative diseases, the effects of tumors and, of course, fractures and dislocations attributable to physical trauma. Throughout the last century, spinal surgeons have tackled the thorny problems associated with addressing and correcting these pathologies using a wide variety of instrumentation and a broad range of surgical techniques. For many years, the use of elongated rigid plates has been helpful in the stabilization and fixation of the lower spine, most particularly the thoracic and lumbar spine. These same plating techniques have found a tougher road towards acceptance by surgeons specializing in treatment of the cervical spine.

The cervical spine can be approached either anteriorly or posteriorly, depending upon the spinal disorder or pathology to be treated. Many of the well known surgical exposure and fusion techniques of the cervical spine are described in a publication entitled *Spinal Instrumentation*, edited by Drs. Howard An and Jerome Cotler. This text also describes instrumentation that has been developed in recent years for application to the cervical spine, most frequently from an anterior approach.

The anterior approach to achieving fusion of the cervical spine has become the most popular approach. During the early years of cervical spine fusion, the fusions occurred without internal instrumentation, relying instead upon external corrective measures such as prolonged recumbent traction, the use of halo devices or minerva casts, or other external stabilization. However, with the advent of the elongated plate customized for use in the cervical spine, plating systems have become predominant for this type of spinal surgery.

It has been found that many plate designs allow for a mono-cortically or bi-cortically intrinsically stable implant. It has also been found that fixation plates can be useful in stabilizing the upper or lower cervical spine in traumatic, degenerative, tumorous or infectious processes. Moreover, these plates provide the additional benefits of allowing simultaneous knurled decompression with immediate stability.

During the many years of development of cervical plating systems, particularly for the anterior approach, various needs for such a system have been recognized. For instance, the plate must provide strong mechanical fixation that can control movement of each vertebral motion segment in six degrees of freedom. The plate must also be able to withstand axial loading in continuity with each of the three columns of the spine. The plating system must be able to maintain stress levels below the endurance limits of the material, while at the same time exceeding the strength of the anatomic structures or vertebrae to which the plating system is engaged.

Another recognized requirements for a plating system is that the thickness of the plate must be small to lower its prominence, particularly in the smaller spaces of the cervical spine. The screws used to connect the plate to the vertebrae must not loosen over time or back out from the

plate. Preferably the plate should be designed to contact the vertebrae for greater stability.

On the other hand, while the plate must satisfy certain mechanical requirements, it must also satisfy certain anatomic and surgical considerations. For example, the cervical plating system must minimize the intrusion into the patient and reduce the trauma to the surrounding soft tissue. In the *Spinal Instrumentation* text, as well as in other documentation in this field, it is stressed that complications associated with any spinal procedure, and most particularly within the tight confines of cervical procedures, the complications can be very devastating, such as injury to the brain stem, spinal cord or vertebral arteries. It has also been found that optimum plating systems permit the placement of more than one screw in each of the instrumented vertebrae.

Many spinal plating systems have been developed in the last couple of decades that address some of the needs and requirements for cervical fixation systems. However, even with the more refined plating system designs, there still remains a need for a system that has universal applicability to all pathologies that can be faced by a spinal surgeon in treating the spine. For example, it has been demonstrated that different degrees of fixation of a bone screw relative to the plate are more advantageous for treating certain pathologies as opposed to other pathologies.

More specifically, it is known that bone screws can be supported in a spinal plate in either a rigid or a semi-rigid fashion. In a rigid fashion, the bone screws are not permitted any micro-motion or angular movement relative to the plate. In the case of a semi-rigid fixation, the bone screw can move somewhat relative to the plate during the healing process of the spine. It has been determined that semi-rigid fixation is preferable for the treatment of degenerative diseases of the spine. In cases where a graft

is implanted to replace the diseased vertebral body, the presence of a screw capable of some rotatation ensures continual loading of the graft. This continual loading avoids stress shielding of the graft, which in turn increases the rate of fusion and incorporation of the graft into the spine.

Similarly, rigid screw fixation is believed to be preferable in the treatment of tumors or trauma to the spine, particularly in the cervical region. It is believed that tumor and trauma conditions are better treated in this way because the rigid placement of the bone screws preserves the neuro-vascular space and provides for immediate stabilization. It can certainly be appreciated in the case of a burst fracture or large tumorous destruction of a vertebra that immediate stabilization and preservation of the disc space and neuro space is essential. On the other hand, the semi-rigid fixation is preferable for degenerative diseases because this type of fixation allows for a dynamic construct. In degenerative conditions, a bone graft is universally utilized to maintain either the disc space and/or the vertebral body itself. In most cases, the graft will settle or be at least partially resorbed into the adjacent bone. A dynamic construct, such as that provided by semi-rigid bone screw fixation, will compensate for this phenomenon.

At present, no plating system is known that allows for the placement of bone screws in either a semi-rigid or a rigid construct with a single plate. While some plates will provide for either one of these screw fixations, no plating system allows the surgeon to use a single plate and to select which of the two types of fixation is desired for the particular spinal pathology and anatomy.

SUMMARY OF THE INVENTION

In order to address the needs left unfulfilled by prior systems, the present invention contemplates a novel system for anterior fixation of the spine utilizing an elongated fixation plate. In one aspect of the invention, the fixation plate is provided with a plurality of holes through which bone screws extend for engagement into a number of vertebrae. In the preferred embodiment, the screw holes include a spherical portion to receive a complementary formed spherical head of the bone screw. The screw holes further include a cylindrical portion integral with the cylindrical portion and opening to the bottom of the plate.

The flexibility of the present invention anterior fixation plating system is accomplished by the provision of a fixed angle and a variable angle screw that can be supported within the same screw hole in the plate. Each of the screws includes a threaded shank for screwing into a vertebra and a spherical head to seat within the spherical recess. Both screws include an intermediate portion between the spherical head and the threaded shank that is configured to reside within the cylindrical portion of the screw hole when the screw is fixed to the plate. The intermediate portion of the fixed angle screw preferably is cylindrical and has an outer diameter sized for a close fit within the cylindrical portion of the screw hole. In this manner, the fixed angle screw is prevented from rotating or pivoting within the screw hole.

The variable angle bone screw includes an intermediate portion that is also preferably cylindrical. However, the cylindrical intermediate portion of the variable angle screw has an outer diameter that is significantly smaller than the diameter of the cylindrical portion of the screw hole. This relative difference in diameters between the screw intermediate portion and the screw hole allows the screw to

assume a range of angles relative to the bottom surface of the plate, even when the screw is locked in position in the plate.

In a further aspect of the invention, a locking assembly is provided for locking the bone screws in the plate, thereby preventing screw back-out. In one embodiment of the invention, the locking assembly includes a washer that resides within a recess in the plate. The recess overlaps at least one screw hole in the plate so that the washer can be seated above the head of the bone screw to hold the screw in place. The locking assembly further includes a threaded set screw that is engaged within a tapped bore concentrically situated within the washer recess. The locking washer is itself configured with a recess so that the head of the locking screw can reside essentially flush within the locking washer.

In a further embodiment, the locking assembly includes a locking washer having cut-outs formed in its outer surface facing the bone screw head. The cut-outs preferably correspond to the shape of the screw hole so that the washer does not overlap the screw hole in the region of the cut-out. The washer is held to the plate by a set screw to permit rotation of the washer from a first position in which the cut-outs are aligned with the screw holes, to a second position in which the outer surface of the washer overlaps the screw holes to lock the screw heads in position. In a further aspect, the washer includes a number of keys projecting from its underside that are configured to mate within corresponding notches formed in the locking washer recess. The notch and key configuration essentially locks the washer in its position overlapping the screw holes.

The fixation plate assembly of the present invention further contemplates various screw hole arrangements that permit clamping of multiple screws by a single locking assembly. Other hole arrangements are provided that offer

several screw fixation options to the surgeon when instrumenting one or more vertebrae. For instance, a four hole arrangement is set forth in which four screw holes a spaced at 90° intervals around a single locking washer and screw assembly. The surgeon can insert either fixed or variable angle screws into any one or more of the four screw holes depending upon the vertebral anatomy.

It is one object of the invention to provide a fixation plate assembly that accommodates either fixed or variable angle screw fixation in a single plate. Another object resides in the provision of a locking assembly that can lock one or more bone screws within the plate.

One benefit achieved by the present invention is that the fixation plate and locking assembly maintain a low profile within the spine. A further benefit is accomplished by the ability to select either a fixed angle or a variable angle screw at any instrumented level and within a single fixation plate.

Other objects and benefits of the invention will become apparent upon consideration of the following written description of the invention, together with the accompanying figures.

DESCRIPTION OF THE FIGURES

FIG. 1 is a top perspective view of an anterior plating system according to one embodiment of the present invention.

FIG. 2 is a side elevational view of the plating system shown in FIG. 1.

FIGS. 3(a)-3(g) are top elevational views of a fixation plate in accordance with the present invention provided in different sizes and configuration.

FIG. 4 is a side elevational view of a fixed-angle bone screw according to one aspect of the present invention.

FIG. 5 is a side elevational view of a variable angle bone screw in accordance with another aspect of the present invention.

FIG. 6 is a top elevational view of one embodiment of an elongated plate for use with the anterior plating system according to the present invention.

FIG. 7 is a side cross-sectional view of the plate shown in FIG. 6 taken along line 7-7 as viewed in the direction of the arrows.

FIG. 8 is an end elevational view of the plate shown in FIG. 6.

FIG. 9 is an end cross-sectional view of the plate shown in FIG. 6 taken along line 9-9 as viewed in the direction of the arrows.

FIG. 10 is a partial side view of a portion of the plate

shown in FIG. 6, particularly illustrating the four-hole pattern for the bone screw holes.

FIG. 11 is a partial side view of an end of the plate in FIG. 6, particularly showing the end hole pattern of bone screw holes.

FIG. 12 is a transverse cross-sectional view of the end hole pattern of the plate in FIG. 6, particularly taken along line 12-12 in FIG. 11 as viewed in the direction of the arrows.

FIG. 13 is an end transverse cross-sectional view of the end of the plate shown in FIG. 6, particularly taken along line 13-13 in FIG. 11 as viewed in the direction of the arrows.

FIG. 14 is a cross-sectional view of one bone screw opening in the end hole pattern of the plate shown in FIG. 6, particularly taken along line 14-14 in FIG. 8 as viewed in the direction of the arrows.

FIG. 15 is an enlarged side elevational view of a locking screw according to one aspect of the present invention.

FIG. 16 is an enlarged side elevational view of a locking washer in accordance with a further aspect of the present invention.

FIG. 17 is a partial cross-sectional view of an end hole pattern of the plate shown in FIG. 6, with the screw and washer of FIGS. 15 and 16, respectively shown in their operative position.

FIG. 18 is a partial cross-sectional view of a plate according to the present invention with the fixed angle bone screws disposed within bone holes in a plate and engaged within a vertebra.

FIG. 19 is an enlarged end cross-sectional view of the plate according to the present invention with variable angle screws disposed in the plate and engaged in a vertebra.

FIG. 20 is an exploded view of an alternative embodiment of a locking screw assembly for use with an anterior plating system according to a further embodiment of the invention.

FIG. 21 is a top perspective view of the components shown in FIG. 20 in the assembled condition with the locking washer shown in its first position.

FIG. 22 is a top perspective view of the locking screw as depicted in FIG. 20, with the locking washer in its second position.

FIG. 23 is a side elevational view of one embodiment of the locking washer used in the assembly of FIGS. 20-22.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended. Any alterations and further modifications in the described device, and any further applications of the principles of the invention as described herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

An anterior plating system or fixation assembly 30 is depicted in FIGS. 1 and 2. In accordance with the present invention, the plating system includes an elongated plate 31 and a number of bone screws 32. The bone screws are held to the plate 31 by way of a plurality of locking assemblies 33. The elongated plate 31 is provided with a plurality of screw holes 34 in a variety of arrangements. The plate also can be divided into vertebral level nodes 35 so that the sides of the plate give a serpentine appearance. In particular, the plate 31 includes recesses between each of the nodes 35 to reduce the outer contour and size of the plate. In addition, the reduced width portion between each of the nodes 35 provides an area of reduced material for additional bending of the plate as may be required by the spinal anatomy.

The plate 31 preferably includes a rounded upper edge 36 that would be in contact with the soft tissue surrounding the spine. The rounded edge 36 reduces the amount of trauma that would be experienced by the surrounding soft tissue. The bottom surface 37 of the plate 31 is preferably configured to contact and engage the vertebral bodies at each of the instrumented levels of the spine. In some embodiments, the bottom surface can be textured to enhance

its grip on the vertebral body.

Referring now to FIGS. 3(a)-3(g), several variations of the elongated plate 31 are depicted. It is understood that the anterior plating system according to the present invention can be readily adapted to fix several vertebrae, of course depending upon the length of the plate and the number and arrangement of screw holes 34. The plate depicted in FIGS. 1, 2 and 3(a) includes five vertebral level nodes 35a so that the plate can be engaged to five vertebrae of the spine. For example, the plate 31a of FIG. 3(a) could be used to fix the vertebrae C1-C5. The elongated plates 31b depicted in FIG. 3(b) is sized and configured to span three or four vertebrae, depending upon the instrumented vertebral levels. In this instance, the plate 31b includes four vertebral level nodes 35b, with two nodes at the opposite ends of the plate and two nodes offset from each other in the middle portion of the plate.

A modification of the plate 31b is depicted in FIG. 3(c). In this case, the plate 31c includes three nodes 35c, with the nodes on the opposite side of the middle portion of the plate being directly aligned at the same vertebral level. The plates of FIGS. 3(d)-3(e), namely plates 31d and 31e, are similar to the plate 31c although their lengths are progressively shorter. The last two plates 31f and 31g, in FIGS. 3(f)-3(g), respectively, provide for instrumentation of two vertebral levels, each having two nodes 35f and 35g, respectively.

In accordance with the present invention, the elongated plates 31a-31g provide a variety of hole patterns at each of the vertebral level nodes 35a-35g. These hole patterns provide, at a minimum, for at least two bone screws to be engaged into each respective vertebra. As discussed above, it has been found that the placement of two or more screws in each vertebral body improves the stability of the construct. It is one object of the present invention not

only to provide for multiple screw placement in each vertebral body, but also to provide means for locking the screws to the elongated plate to prevent backout or loosening of the bone screws. Consequently, in a further aspect of the invention, various hole patterns are provided that address these objects. One pattern is an end hole pattern 38, as shown at the ends of plate 31 in FIG. 1 and plate 31a in FIG. 3(a). In this arrangement, two screw holes 34 are laterally disposed at a single node 35a. A single locking assembly is disposed between the two screw holes 34 and is configured to lock bone screws disposed within each respective hole. A similar arrangement is provided by the middle hole pattern 39 in which two screw holes are situated at a single vertebral level. A locking assembly is disposed between the two bone screw holes and is configured to lock bone screws within the respective holes in the same manner as screws are locked in the end hole pattern 38.

The present invention contemplates a plate carrying four-hole patterns. The four-hole pattern 40 illustrated in FIG. 1 and FIGS. 3(a) and 3(b), provides four bone screw holes 34 in a diamond pattern. A single locking assembly 33 is centrally disposed between all of the bone screw holes so that bone screws within the respective holes are simultaneously locked by the single locking assembly. In the five node plate 31a of FIG. 3(a), two such four-hole patterns 40 are provided. In the three-node plate 31d of FIG. 3(d), only a single four-hole pattern 40 is required. It can be appreciated that the four-hole pattern 40 provides a great degree of flexibility to the surgeon in determining how many bone screws 32 will be engaged into a single vertebra, and in what arrangement. For example, as shown in FIG. 1, two screws are situated in the laterally opposite screw holes at the vertebral level node 35. Alternatively, bone screws could be placed in the longitudinally opposite

screw holes oriented along the length of the plate 31a. Less conventional arrangements contemplate bone screws being placed in immediately adjacent screw holes 34, or placing three bone screws in three of the holes of the four-hole pattern 40. Again, the selection of bone screws and their arrangement can be left to the surgeon and will be based upon the type of correction or fixation required and the anatomy of the particular instrumented vertebra.

A further arrangement for screw holes 34 is provided by the four-hole cluster 41 depicted in FIGS. 3(b) and 3(c). In the four-hole cluster 41 in plate 31b, two hole pairs 41a and 41b are provided. Each of the hole pairs includes its own locking assembly to lock the two screws into the screw bores of the respective hole pairs. As shown in FIG. 3(b), the orientation of the particular hole pairs provides one screw hole from each pair generally laterally relative to each other in a single vertebra. The other of the bone screw holes in each respective pair is longitudinally offset from the central screw holes, being disposed closer to the ends of the plate 31b. In this manner, the two central holes of each of the two holes pairs can be engaged in a single vertebra, while the remaining screw holes of the hole pairs 41a and 41b can be disposed in the superior and inferior adjacent vertebrae. Most preferably, however, each of the screw holes in the four-hole cluster 41 is generally oriented over or slightly offset from a single vertebra. The surgeon then has the option to selected any of the screw holes in the two hole pairs 41a or 41b that is optimally aligned over the vertebra.

A similar arrangement is found in the plate 31C which includes a four-hole cluster 42. In this case, it can be seen that the four-hole cluster 42 includes two hole pairs 42a and 42b, in a manner similar to the four-hole cluster 41 of FIG. 3(b); however in this case, the hole pairs are arranged closer to each other, principally because the plate

31c is shorter than the plate 31b. In both of the four-hole clusters 40 and 41, the locking assemblies are provided to lock only a pair of bone screw holes rather than all four holes with a single locking assembly.

The invention further contemplates a three-hole pattern, such as pattern 43 provided in the plate 31f in FIG. 3(f). In this pattern 43, a single locking assembly is used to fix three bone screws within the respective screw holes. A five-hole pattern 44 is provided on plate 31g, as shown in FIG. 3(g). In this five-hole pattern, a single hole is arranged centrally between four outlying holes. Two locking assemblies 33 are provided to lock a pair of the outlying four screw holes together with the central hole. In this configuration, the central hole is held in place by two locking assemblies, while each of the outlying four holes is held in place by a single locking assembly.

In one important aspect of the present invention, the bone screw 32 can either constitute a fixed angle screw 50, as shown in FIG. 4, or a variable angle screw 60, as shown in FIG 5. Turning first to FIG. 4, the fixed angle screw 50 includes a threaded shank 51. The threaded shank is preferably configured to engage the cancellous bone of a vertebral body. The threaded shank can also include self tapping threads, although the specific illustrated embodiment requires prior drilling and tapping of the vertebral body for insertion of the fixed angle screw 50. The screw 50 includes an intermediate portion 52 that is disposed between the threaded shank 51 and the head 54 of the screw. The threaded shank 51 extends into the intermediate portion 52 by a thread run-out 53, according to standard thread machining practices. As can be seen from FIG. 4, the intermediate portion 52 includes a short segment that does not bear any threads. This short segment has an outer diameter D_1 that will assume significance during consideration of the details of the elongated plate 31

discussed herein.

The head 54 of the fixed angle screw 50 includes a tool recess 55 that is configured to receive a driving tool. In one specific embodiment, the tool recess 55 can be a hex recess, or in an alternative embodiment, a TORX* type recess. The head 54 includes a truncated or flattened top surface 56 and a spherical surface 57 between the top surface 56 and the intermediate portion 52. The head 54 includes a height H_1 between the top surface 56 and the intermediate portion 52.

In one specific embodiment, the intermediate portion 52, and more specifically the segment between the thread run-out 53 and the head 54, has a height of 1.2mm and a diameter of 4.05mm. The height H_1 of the head 54 in this specific embodiment has a dimension of 2.6mm. In this specific embodiment, the dimensions of the head 54 and intermediate portion 52 are calibrated for length of the threaded shank 51 of between 10mm and 20mm. In this specific embodiment, the bone screws are preferably configured for engagement in the cervical spine. In another aspect of the specific embodiment, the root diameter of the threaded shank 51 is tapered over the first four convolutions to the final root diameter, which is about 2.43mm in the specific embodiment.

Turning to FIG. 5, the details of the variable angle screw 60 can be seen. Like the fixed angle screw 50, the variable angle screw 60 includes a threaded shank 61 and an intermediate portion 62. However, in contrast to the fixed angle screw 50, the intermediate portion 62 has an outer diameter D_2 that is approximately equal to the root diameter of the threaded shank 61. In other words, the diameter D_2 of the intermediate portion 62 of the variable angle screw 60 is less than the diameter D_1 of the intermediate portion 52 of the fixed angle screw 50. Like the fixed angle screw 50, the threads of the shank 61 run out into the intermediate portion 62, leaving the portion 62

with a threaded height of about 0.8mm.

The variable angle screw 60 also includes a head 64 having a tool recess 65 defined from the truncated top surface 66. The head 64 also includes a spherical surface 67 disposed between the top surface 66 and the intermediate portion 62. The head 64 of the variable angle screw 60 has a height H_2 between the top surface and the intermediate portion that is greater than the height H_1 of the head 54 of the fixed angle screw 50.

In the specific embodiment of the variable angle screw 60, the head 64 has a height H_2 of about 3.3mm. This greater height is attributable to the smaller diameter D_2 of the intermediate portion 64 relative to the diameter D_1 of the intermediate portion 52 of the fixed angle screw 50. Both the head 54 and the head 64 of the respective screws have a comparable outer diameter, which is 4.88mm in the specific embodiment. In the case of the variable angle screw, the diameter of the spherical surface 67 continues around a greater arc because the intermediate portion 62 has a smaller diameter. In one specific embodiment, the intermediate portion 62 has a diameter D_2 of 2.9mm, compared to the 4.05mm diameter D_1 for the fixed angle screw 50.

Like the fixed angle screw 50, the variable angle screw 60 can be preferably provided in lengths between 10mm and 20mm, for use at different locations in the spine.

The engagement of the bone screws 50 and 60 to the elongated plate 31 require further discussion of the details of the plate itself. These details can be discerned with reference to FIGS. 6-14. In FIG. 6, the longer plate 31a is depicted, although it is understood that the various geometric structural aspects of this plate are repeated among each of the plates 31b-31g. As discussed previously, the plate 31a includes undulating edges, with the peaks of the undulation corresponding to the vertebral level nodes

35. The plate material between the nodes is reduced to minimize the bulk of the plate and to provide a thinner plate width in areas that may require additional bending for implantation. In the specific embodiment, a plurality of screw holes 34 is provided throughout the length of the plate and in various patterns. In the illustrated embodiment of FIG. 6, the holes are oriented in end hole patterns 38 at opposite ends of the plate, middle hole pattern 39 centrally located in the plate, and two four-hole patterns 40 disposed between the end hole patterns 38 and the middle hole pattern 39. In each case, the hole patterns require a locking screw assembly 33. Consequently, the plate 31a, along with all the other plate design contemplated by the present invention, includes tapped bore 70 situated within a concentric locking recess 71. (See FIG. 7). As shown in FIGS. 6 and 7, the locking recess 71 intersects or overlaps adjacent bone screw holes 34. In the case of the end hole pattern 38, the locking recess 71 overlaps the two screw holes, while in the case of the four-hole pattern 40, the locking recess 71 overlaps the four holes 34 arranged in a diamond pattern.

To accommodate the anterior application of this fixation plate assembly 30, the plate is curved in two degrees of freedom. Specifically, the bottom surface 37 of the plate can be curved along a large radius R, as shown in FIG. 7, to accommodate the kyphotic curvature of the cervical spine. In addition, the bottom surface 37 forms a medial/lateral curvature L, as shown in FIG. 9, to correspond to the curvature of the vertebral body. It is understood that the plate 31a can be bent along its longitudinal length between the vertebral level nodes 35, as required to accommodate the particular spinal anatomy and vertebral pathology.

The screw holes 34 in the plate 31a are defined by a spherical recess 75 (see FIGS. 7 and 9) having a diameter measured about an axis 75a intersecting the elongated plate

31a. (See FIGS. 11 and 12). In a further aspect of the invention, the screw holes 34 include a cylindrical bore 77 communicating between the spherical recess 75 and the bottom surface 37 of the plate 31. The cylindrical bore 77 defines a diameter along the axis 75a. To facilitate insertion of drill guides, drills and the bone screws 32, each screw hole 34 includes a flared recess 79. The flared recess is preferably formed as a tapered counter-sink along an axis 79a (see FIGS. 11 and 13). This flared recess 79 overlaps the locking recess 71 of the locking assembly 33 at a recess overlap 80, shown best in FIGS. 7, 9 and 13.

In one specific embodiment, the spherical recess 75 is defined at a diameter of 5.0mm, which is slightly larger than the diameter of the heads 54, 64 of the bone screws 50, 60. The cylindrical portion of the screw holes 34 is defined at a diameter of 4.1mm, in the specific embodiment, which is again slightly larger than the diameter D_1 of the intermediate portion 52 of the fixed angle screw 50. It should be understood, of course, that the diameter of the cylindrical bore 77 is significantly larger than the diameter D_2 of the intermediate portion 62 of the variable angle screw 60.

Again in the specific embodiment, the axis 75a of both the spherical recess 25 and the cylindrical bore 77 is oriented generally normal to the bottom surface 37 of the plate 31a, when viewed in the direction of the longitudinal axis of the plate. In other words, the axis 75 is normal to the plate in the direction of the medial/lateral curvature L of the plate. On the other hand, the orientation of the screw holes 34 can vary between the vertebral level nodes 35, and most particularly when considering the end hole patterns 38. In this specific embodiment, the flared recess 79, and specifically its axis 79a, can be colinear with the axis 75a of the recess 75, for the hole patterns in the interior of the elongated plate 31a. For example, as shown

in FIG. 6, the flared recess 79 can be approximately concentric with the screw holes 34 for the middle hole pattern 39. On the other hand, the flared recess 79, and specifically the axis 79a, at the end hole patterns 38, are offset at an angle A, as depicted in FIG. 14. In particular, the axis 75a of the spherical recess is offset at an angle A of about 12 degrees relative to a perpendicular from the bottom surface 37 of the plate 31a. In this manner, the bone screws will be directed outwardly toward the end of the plate upon insertion into the screw holes 34.

The details of the locking assembly 33 can be gleaned from consideration of FIGS. 15-17. In this specific embodiment, the locking assembly 33 includes a locking screw 85 having machine threads 86. In one specific embodiment, the locking screw 85 terminates in a sharp point 86a to permit penetration of the vertebral body. The head 87 of the locking screw 85 includes a lower conical surface 88 and a tool recess 89 defined therein for receiving a driving tool.

The locking assembly 33 also includes a washer 90 having an outer surface 91. In the specific preferred embodiment, the outer surface 91 is defined by a curved convex surface 92. The washer 90 also includes a screw bore 93 extending therethrough in communication with a tapered bore 94. The tapered bore 94 has a complementary mating configuration relative to the conical surface 88 of the head 87 of locking screw 85. The mating conical features between the locking screw and washer provides a self-centering capability for the washer as the locking screw is tightened onto the plate. The screw bore 93 is sized to receive the machine threads 86 therethrough for engagement with the tapped bore 70 of the plate 31a, as shown in FIG. 17. As illustrated in FIG. 17, the outer surface 91 of the washer 90 intersects the recess overlap 80 between the flared recess 79 and the

respective spherical recess 75 of the adjacent screw holes 34. In a specific embodiment, the locking recess 71 has a diameter of 6mm to accept the washer 90 having an outer diameter of 5.3mm. Again in this specific embodiment, the curved convex surface 92 of the washer 90 is curved at a radius of about 2.5mm so that the lowermost portion of the washer has a smaller diameter of about 4.3mm.

Referring now to FIGS. 18 and 19, the use of the fixation plate assembly 30 is illustrated. In FIG. 18, a pair of fixed angle screws 50 are disposed within respective bores 34 so that the threaded shanks 51 project beyond the lower surface 37 of the plate 31 and into the vertebral body V. The intermediate portion 52 of the fixed angle screw 50 extends through the cylindrical bore 77 of the screw holes 34. The spherical surface 57 of the head 54 of the screw contacts the spherical recess 75 of the screw hole 34 as the fixed angle screw 50 is threaded into the vertebral body V. Once the screw 50 is completely seated within the spherical recess 75, the intermediate portion 52 provides a snug relationship relative to the cylindrical bore 77 so that the fixed angle screw 50 is not able to pivot or translate relative to the plate 31.

In order to ensure secure fixation of the screw 50 within plate 31, the locking assembly 33 is tightened onto the heads 54 of the two bone screws 50. In particular, the locking screw 85 is threaded into the tapped bore 70 to draw the washer 90 into contact with the screw heads. The convex surface 92 seats against the spherical surface 57 of the bone screw heads 54 to firmly seat the screw heads within the plate spherical recess 75. Preferably, the locking washer 90 will advance sufficiently far into the locking recess 71 to rest substantially flush with the top surfaces 56 of the bone screws 50. In the locked position, the washer 90 does not bottom out within the locking recess 71.

In a further aspect of the invention, the locking

assembly 33 is loosely fixed on the plate 31 so that the surgeon need not fiddle with the locking assembly when the plate is engaged to a vertebra. In particular, the locking screw 85 is pre-threaded through the locking washer 90 and into the tapped bore 70 until about three or fewer threads of the locking screw project below the bottom surface 37 of the plate. The locking screw 85 is then staked at the thread nearest the plate so that the screw cannot be removed or backed out through the tapped bore 70. Of course, the locking screw 85 can be advanced further through the bore 70- when it is necessary to enable the locking assembly 33. As previously mentioned, the sharp point 86a of the locking screw 85 is preferably configured to penetrate the cortical bone. With the locking screw staked to the plate, the sharp point 86a will penetrate the vertebra V when the plate 31 is initially positioned on the bone. In this instance, the locking screw 85 helps locate and temporarily stabilize the plate on the vertebra V as the bone screws 50 are implanted into the bone. This temporary location feature provided by the locking screw 85 can also be used when a drill guide is used to drill and tap the vertebra to receive the bone screws 50.

The locking assembly 33 is configured so that the washer 90 can be moved clear of the screw holes 34 when the locking screw 85 is staked to the plate 31. Thus, even with the locking assembly 33 in its loosened position, the bone screws 50, 60 can still be inserted into the screw holes 34, preferably by pulling the washer 90 away from the plate 31.

The use of the variable angle bone screw 60 is depicted in FIG. 19. The locking assembly 33 functions as described above to lock the heads 64 of the variable angle screws 60 within the plate 31. Specifically, the convex surface 92 of the washer 90 contacts and applies pressure to the spherical surfaces 67 of the respective bone screws 60. However, with the variable angle screws 60, the intermediate portion 62

does not fit snugly within the cylindrical bore 77 of the screw holes 34. Thus, even with the head 64 of each screw 60 residing solidly within the spherical recess 75, the bone screw 60 can still be angulated relative to the plate and to the axis of the spherical recess 75 and cylindrical bore 77. It is understood that the degree of angulation is restricted by the difference in diameters between the cylindrical bore 77 and the intermediate portion 62 of the variable angle screw 60. In one preferred embodiment, the relative diameters permit angulation of up to 20° from the axis 75a of the recess 75 and bore 77.

During implantation, the variable angle capability of the screw 60 allows the surgeon to place the bone screw within the vertebra at any angle within the defined angulation limits (20° in one specific embodiment). Thus, the variable angle screw 60 provides greater flexibility than does the fixed angle screw 50 for orienting the bone screw relative to the anatomy of the vertebra. Moreover, this variable angle capability allows a limited degree of micro-motion between the screw and the plate when the fixation assembly 30 is implanted within a patient. In other words, as the spine is loaded and as load is transmitted through the screws and plate, the plate and vertebra may translate relative to each other. The variable angle screw 60 accommodates this relative movement by pivoting within the spherical recess 75. On the other hand, the fixed angle screw 50 prevents this relative movement. The choice between using a fixed or a variable angle screw can be left to the surgeon depending upon the pathology being treated. The fixation plate assembly 30 according to the present invention allows this choice to be made at any point during the surgical procedure.

A further embodiment of the present invention is depicted in FIGS. 20-23. In this embodiment, an alternative locking mechanism is provided. A plate assembly 100

includes an elongated plate 101 receiving bone screws 102. A locking assembly 103 is provided to lock the bone screw within the plate. The plate 101 defines a spherical recess 105 to receive the spherical head 115 of the bone screw. The threaded shank 114 of the bone screw projects through the recess. It is understood that the bone screw 102 and spherical recess 105 can be similar to the like components described above.

In accordance with this embodiment, the plate further includes a tapped bore and concentric locking recess 107 disposed adjacent the spherical recess 105 for the bone screw. The spherical and locking recess contact at a locking overlap 108. A notch 110 extends transversely across the locking recess 107 in this embodiment.

The locking assembly 103 includes a locking washer 120 and locking screw 121. Like the prior locking screw, the screw 121 includes machine threads 122 and an enlarged head 123. The head sits within a recess 124 in the washer 120, with the machine threads 122 projecting through a bore 125. The machine threads 122 are configured to engage the tapped bore 106 of the plate 101. The locking screw 121 can be staked onto the plate 101 as discussed with respect to the prior embodiment.

The locking washer 120, while functioning similar to the washer of the prior embodiment, offers a different construction than the previous washer. Like the washer 90, the locking washer 120 includes an outer circumferential surface 127 that is preferably convex to mate with a spherical head of the bone screw 102. However, in one modification, the washer 120 includes cut-outs 128 in the circumferential surface 127. The cut-outs 128 are arranged to coincide with the screw recesses 105 when the locking washer is in a first position, as illustrated in FIG. 21. This structure of the washer 120 allows the washer to remain clear of the recess 105 for unimpeded insertion of the bone

screw 102.

In certain embodiments, the washer 120 is provided with two such cut-outs at diametrically opposite positions on the washer. Most preferably, the cut-outs 128 are aligned with the relative orientation of screw holes 105 in the plate 101. For example, a washer 120 adapted for a three hole pattern 43, as depicted in FIG. 3(f), would have three cut-outs 128 at 120° intervals. Similarly, a locking washer 120 modified for use with the four hole pattern 40 of FIG. 3(a) would have four cut-outs 128 spaced 90° apart on the circumferential surface 127 of the washer.

Once the bone screws have been implanted through the appropriate screw recesses 105, the locking washer 120 can be rotated into its locking position shown in FIG. 22. In this position, the cut-outs 128 are rotated away from the screw recesses 105 so that the washer, and more particularly the outer circumferential surface 127, overlaps the screw recess 105. In a further modification from the prior washer, the washer 120 includes a number of keys 129 on the underside of the washer. The keys are configured to sit within a corresponding notch 110 in the plate 101 when the locking washer is in the locking position shown in FIG. 22. Once the bone screws have been implanted and the locking washer 120 has been rotated into it locking position, the keys 129 fall into the notches 110 to fix the position of the washer while the locking screw 121 is tightened.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

a first bone engaging fastener having a first elongated shank defining bone engaging threads thereon, a first enlarged head and a first intermediate portion between said shank and said head, said first shank having an outer diameter less than said second diameter so said first bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said first enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole, and said first intermediate portion having a third diameter that is substantially smaller than said second diameter, whereby said first head of said first bone engaging fastener can be pivoted within said recess portion of said at least one hole so that said first bone engaging fastener can assume a plurality of angles relative to said bottom surface of said plate; and

a second bone engaging fastener having a second elongated shank defining bone engaging threads thereon, a second enlarged head and a second intermediate portion between said shank and said head, said second shank having an outer diameter less than said second diameter so said second bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said second enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole, and said second intermediate portion having a

substantially cylindrical portion with a fourth diameter that is approximately equal to said second diameter, whereby said second head of said second bone engaging fastener cannot be pivoted within said recess portion of said at least one hole so that said second bone engaging fastener can assume a fixed orientation relative to said bottom surface of said plate.

2. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head, said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

a locking screw assembly for locking said head of said bone engaging fastener within said recess portion of said

plate, including;

a fastener bore defined in said plate adjacent said at least one hole;

a washer defining a central aperture and a recess communicating with said aperture, said washer further having an outer circumferential surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole; and

a locking fastener having a head configured to be recessed within said recess of said washer and an elongated shank extending through said central aperture and configured to engage said fastener bore of said plate.

3. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head, said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

a locking screw assembly for locking said head of said bone engaging fastener within said recess portion of said

plate, including;

a fastener bore defined in said plate adjacent said at least one hole;

a washer defining a central aperture and a recess communicating with said aperture, said washer further having an outer circumferential surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole, said outer circumferential surface having a concave curvature substantially corresponding to said partially spherical surface of said head of said bone engaging fastener; and

a locking fastener having a head configured to engage said washer and an elongated shank extending through said central aperture and configured to engage said fastener bore of said plate.

4. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head, said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

a locking screw assembly for locking said head of said

bone engaging fastener within said recess portion of said plate, including;

a fastener bore defined in said plate adjacent said at least one hole;

a washer defining a central aperture and a bottom surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole, said washer further defining a circumferential surface having a first portion overlapping said at least one hole when said washer is in a first position relative to said at least one hole and having a second portion that does not overlap said at least one hole when said washer is rotated from said first position to a second position, whereby said bone engaging fastener can be inserted through said at least one hole with said washer engaged to said plate when said washer is in said second position; and

a locking fastener having a head configured to be recessed within said recess of said washer and an elongated shank extending through said central aperture and configured to engage said fastener bore of said plate.

5. A bone fixation system comprising:

an elongated plate having a top surface and a bottom surface and defining a plurality of holes between said surfaces, at least one of said plurality of holes including a spherical recess portion adjacent said top surface having a first diameter and defining an opening at said bottom surface having a second diameter less than said first diameter;

a bone engaging fastener having a elongated shank defining bone engaging threads thereon, a enlarged head and an intermediate portion between said shank and said head,

said shank having an outer diameter less than said second diameter so said bone engaging fastener can be inserted through said at least one hole from said top surface of said plate, said enlarged head defining a partially spherical surface complementary to said spherical recess of said at least one hole; and

a locking screw assembly for locking said head of said bone engaging fastener within said recess portion of said plate, including;

a fastener bore defined in said plate adjacent said at least one hole;

a notch defined in said plate adjacent said fastener bore;

a washer defining a central aperture and a recess communicating with said aperture, said washer further having an outer surface configured to contact said head of said bone engaging fastener when said bone engaging fastener is extended through said at least one hole, said washer further including a key adjacent said central aperture configured to seat within said notch in said plate to prevent rotation of said washer relative to said plate; and

a locking fastener having a head configured to be recessed within said recess of said washer and an elongated shank extending through said central aperture and configured to engage said fastener bore of said plate.

6. A bone fixation system comprising:

four bone engaging fasteners, each having an enlarged head and a threaded shank;

an elongated plate sized to span between at least three vertebrae, said plate defining two sets of two holes, each configured to receive said threaded shank of said bone engaging fasteners therethrough, a first set having a first

hole aligned over a first vertebra and a second hole aligned over a second vertebra when said plate spans the vertebrae, and a second set having a third hole adjacent said second hole and aligned over the second vertebra, and a fourth hole aligned over a third vertebra adjacent the second vertebra; and

a pair of locking screw assemblies, one each for each of said two sets of two holes, each of said locking screw assemblies having a washer configured to overlap each of said two holes of said first and second sets when a bone engaging fastener extends through a corresponding one of said holes.

7. A bone fixation system comprising:

four bone engaging fasteners, each having an enlarged head and a threaded shank;

an elongated plate sized to span between at least three vertebrae, said plate defining a sets of four adjacent holes, each configured to receive said threaded shank of said bone engaging fasteners therethrough; and

a locking screw assembly having a washer configured to overlap each of said four holes when a bone engaging fastener is extended through a corresponding one of said four holes.

8. A bone fixation system comprising:

five bone engaging fasteners, each having an enlarged head and a threaded shank;

an elongated plate sized to span between at least three vertebrae, said plate defining three sets of two holes, each configured to receive said threaded shank of said bone engaging fasteners therethrough, a first set having two holes aligned over a first vertebra, a second set having one hole aligned over a second vertebra when said plate spans the three vertebrae, and a third set having two holes

aligned over the third vertebra; and

a pair of locking screw assemblies, a first one of said locking screw assemblies disposed between said first set and said second set of holes and including a first washer configured to overlap each of said two holes of said first set and said one hole of said second set when a bone engaging fastener extends through a corresponding one of said holes, and a second one of said locking screw assemblies disposed between said second set and said third set of holes and including a second washer configured to overlap said one hole of said second set and each of said two holes of said third set when a bone engaging fastener extends through a corresponding one of said holes.

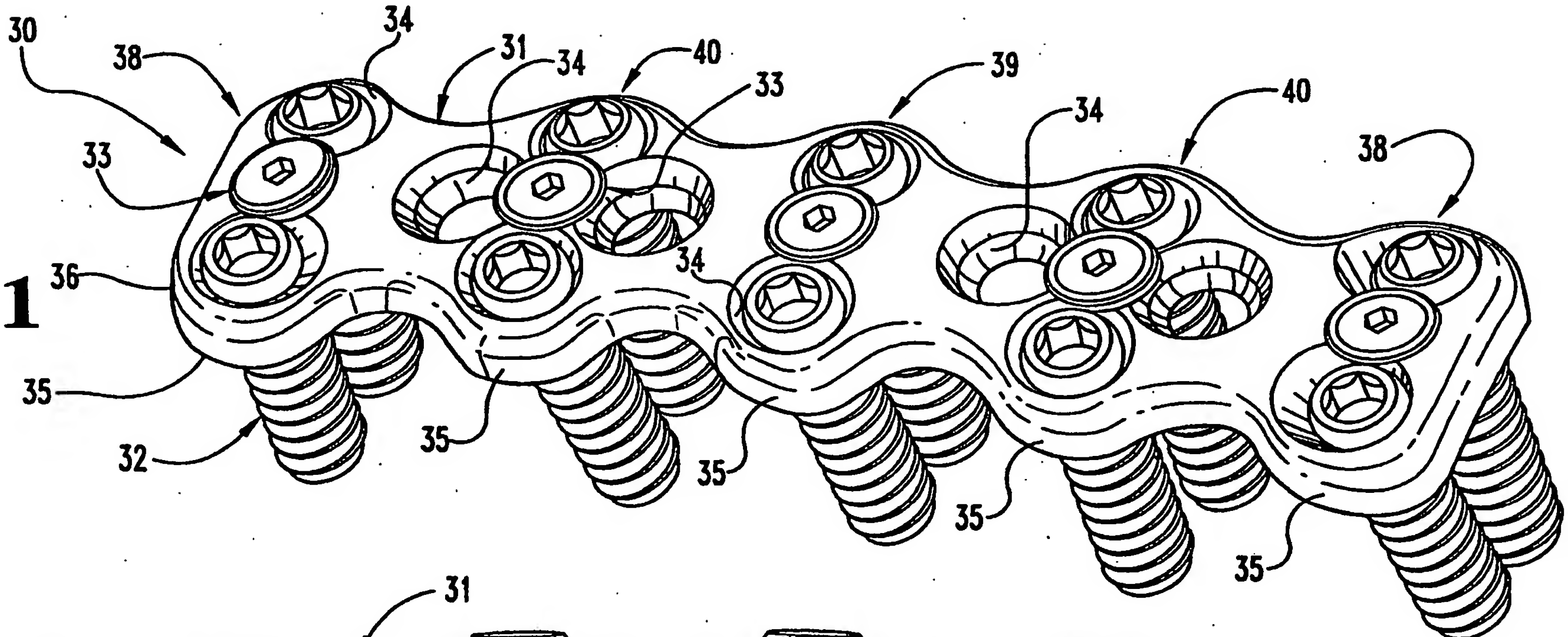


Fig. 1

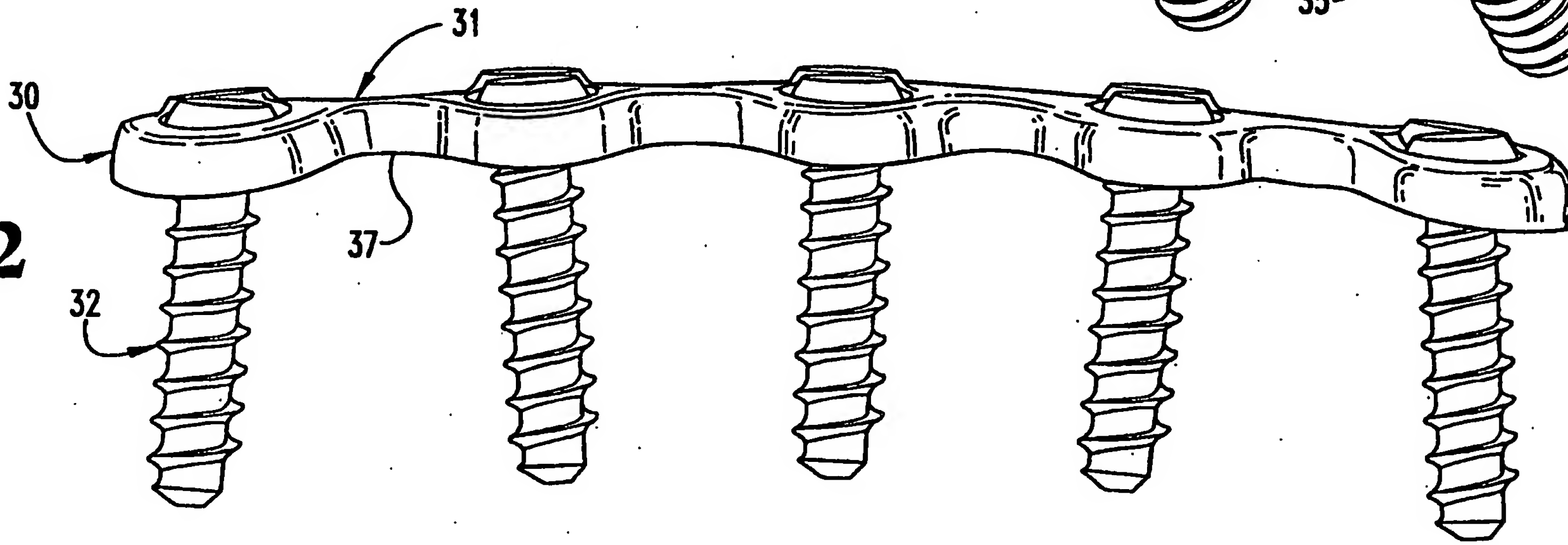


Fig. 2

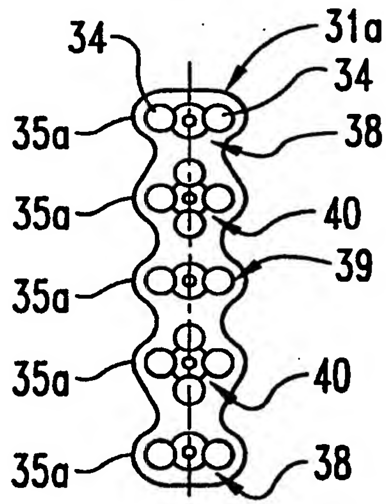


Fig. 3a

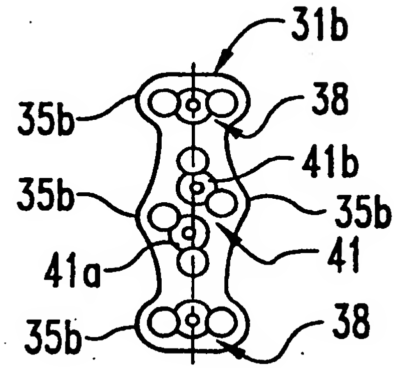


Fig. 3b

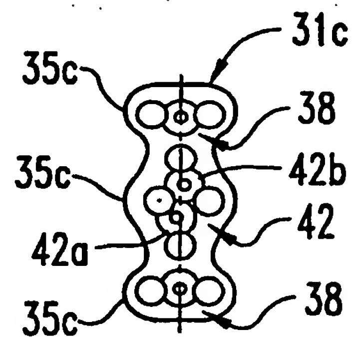


Fig. 3c

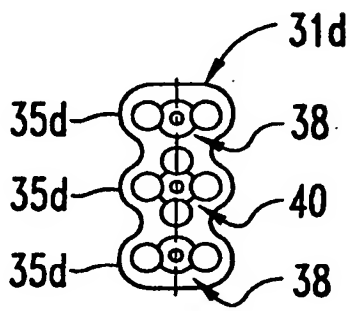


Fig. 3d

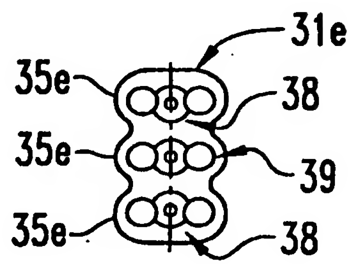


Fig. 3e

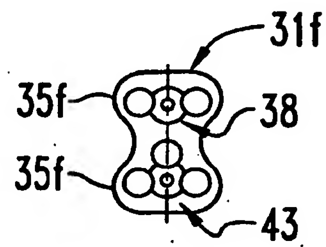


Fig. 3f

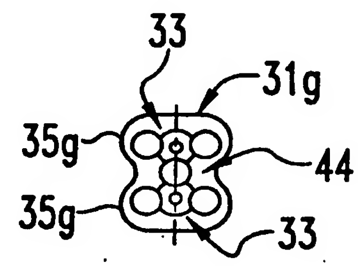


Fig. 3g

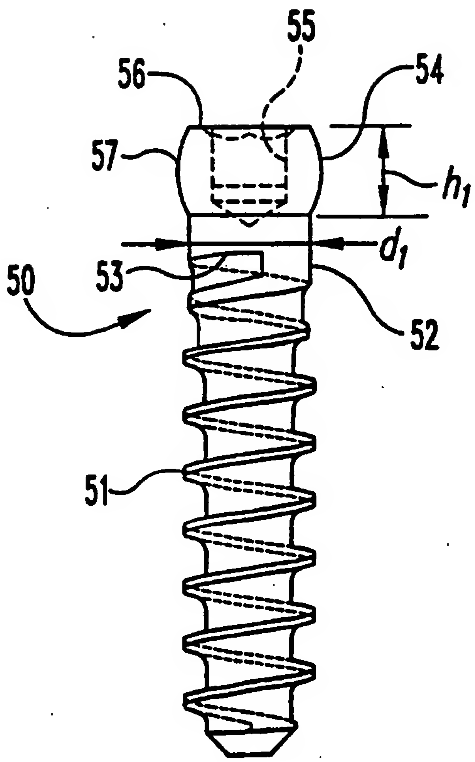


Fig. 4

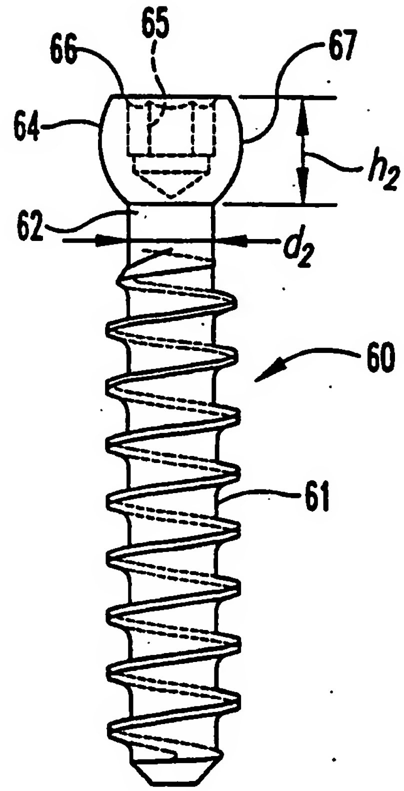


Fig. 5

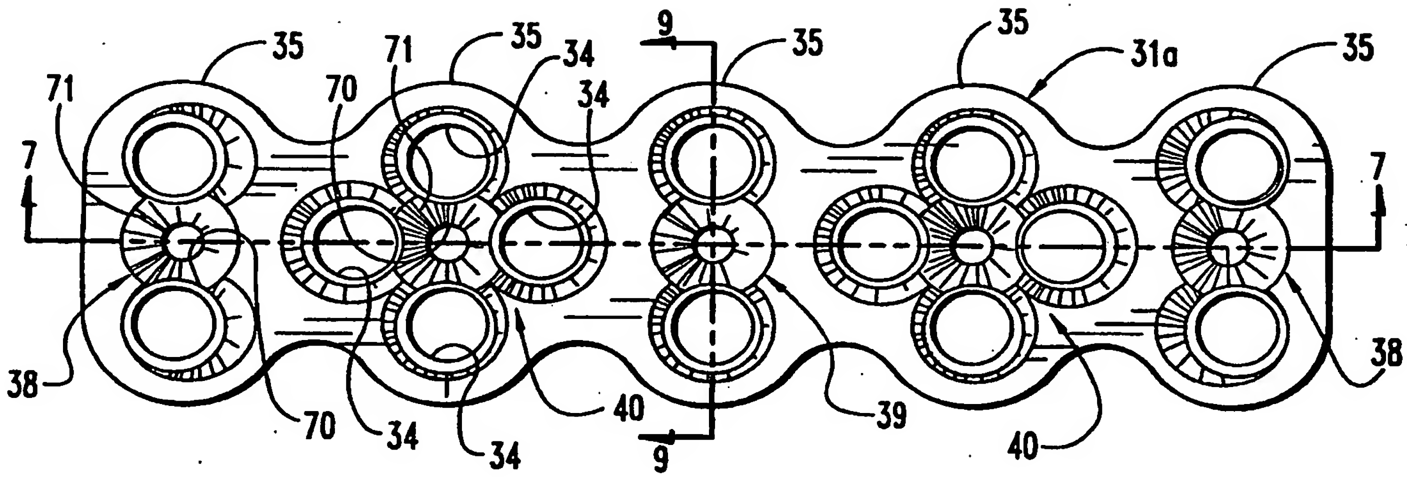


Fig. 6

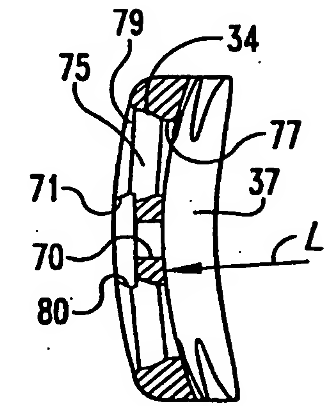


Fig. 9

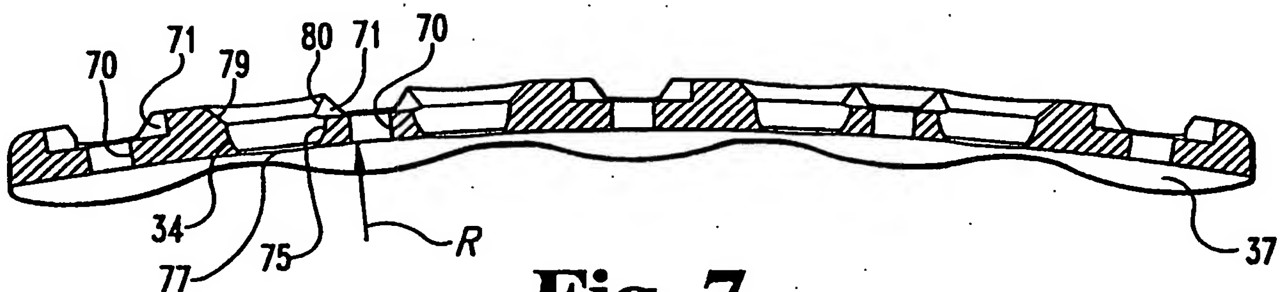


Fig. 7

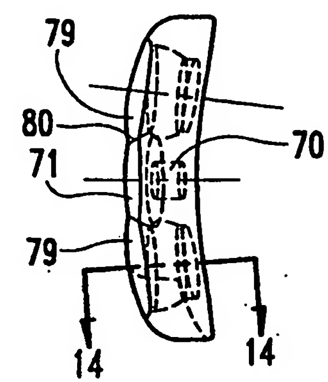


Fig. 8

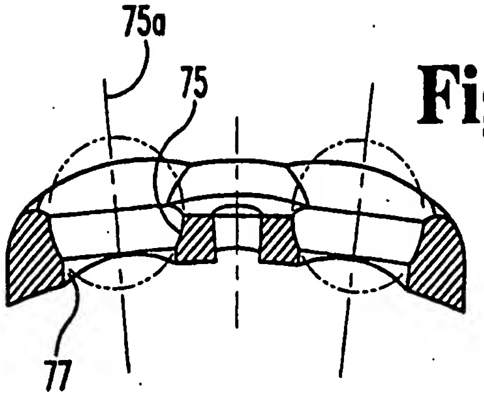


Fig. 12

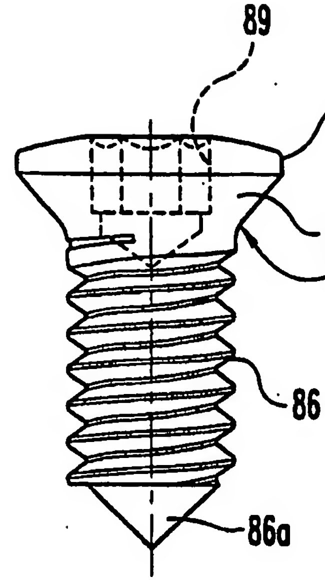


Fig. 15

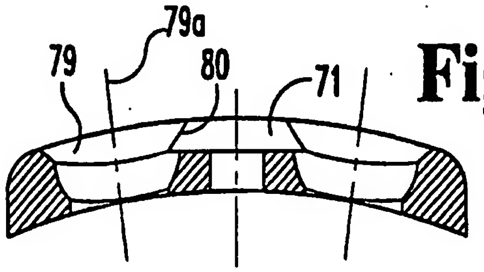


Fig. 13

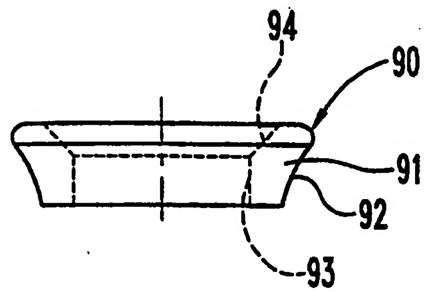


Fig. 16

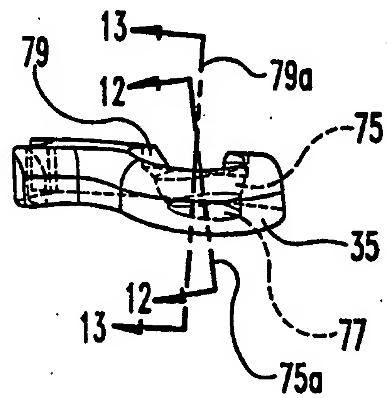


Fig. 11

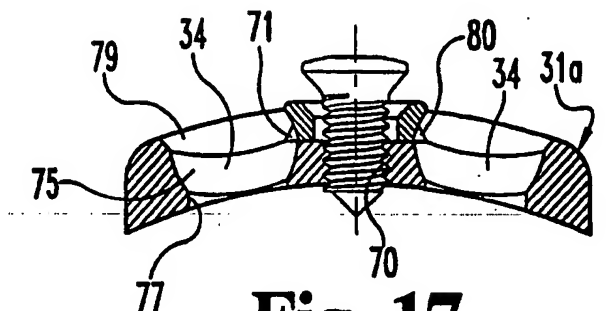


Fig. 17

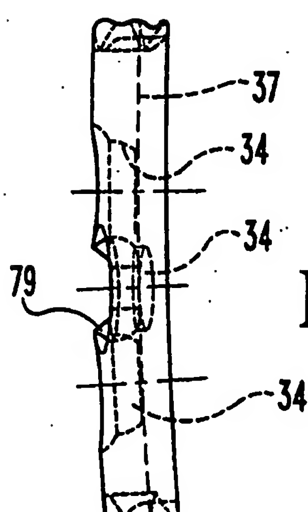


Fig. 10

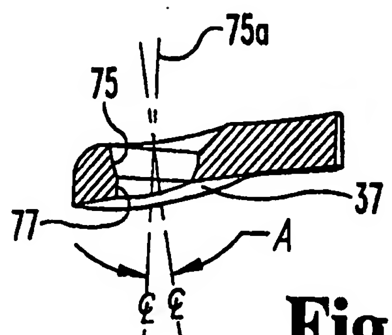
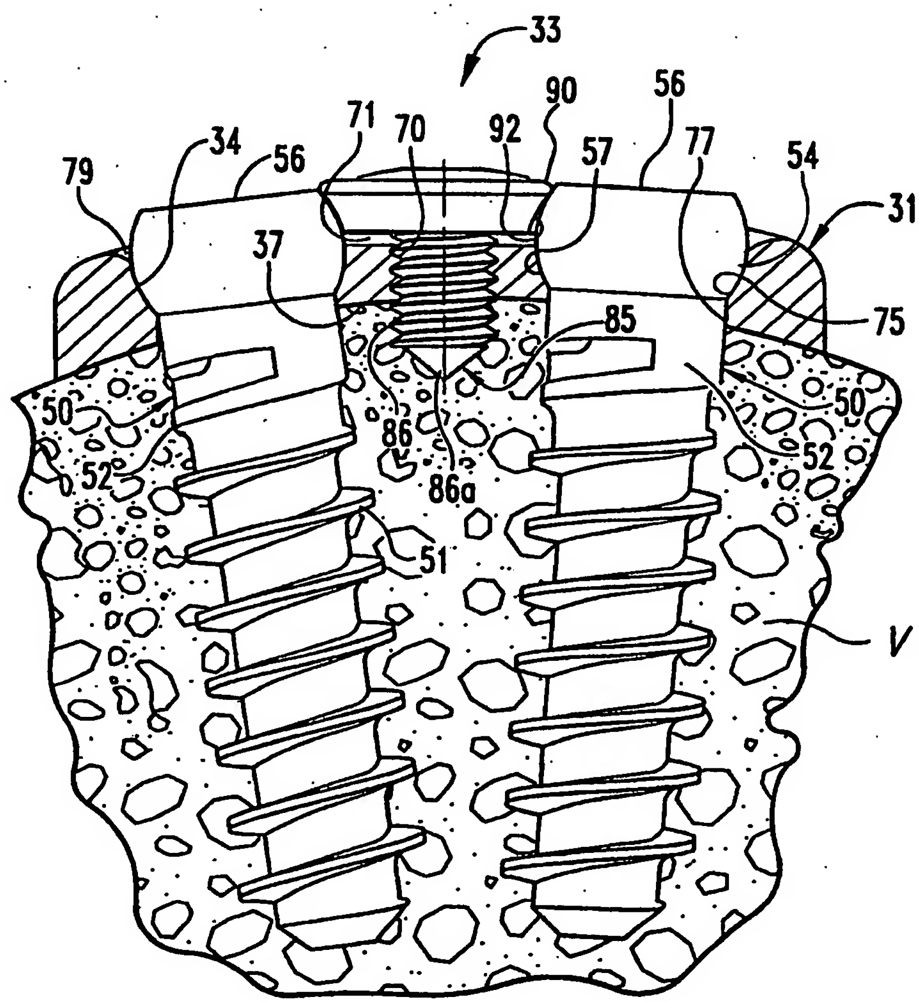


Fig. 14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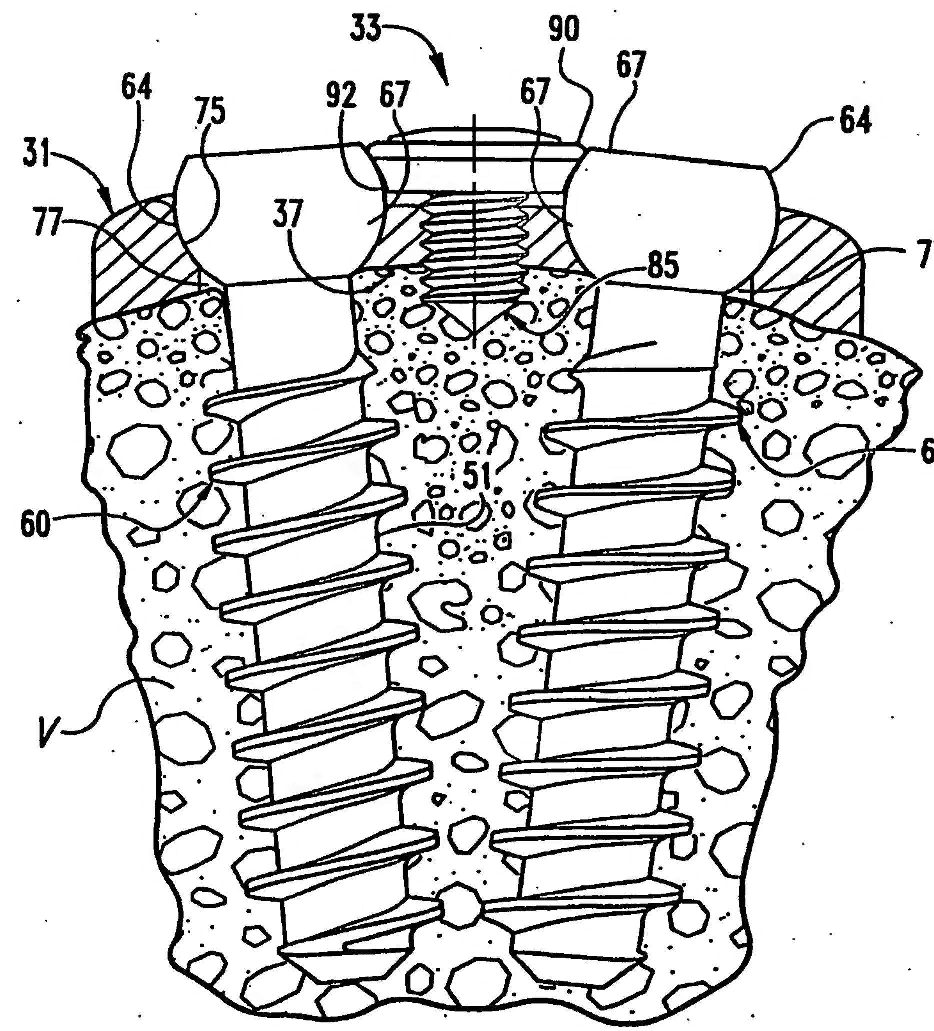
V

Fig. 18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V

Fig. 19

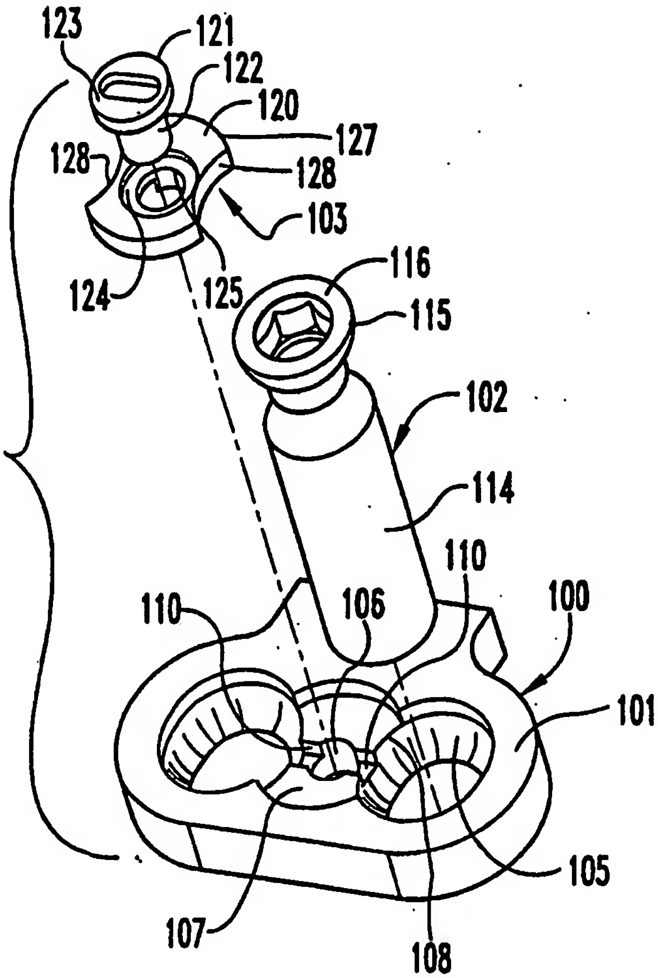

Fig. 20

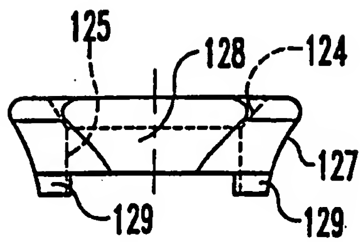

Fig. 23

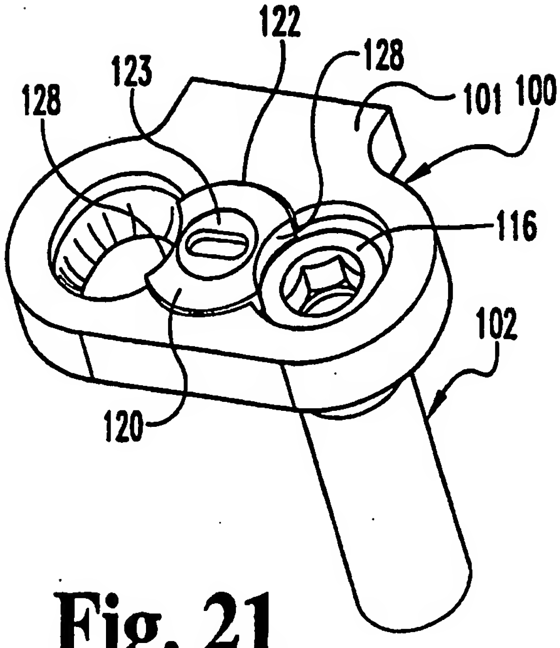

Fig. 21

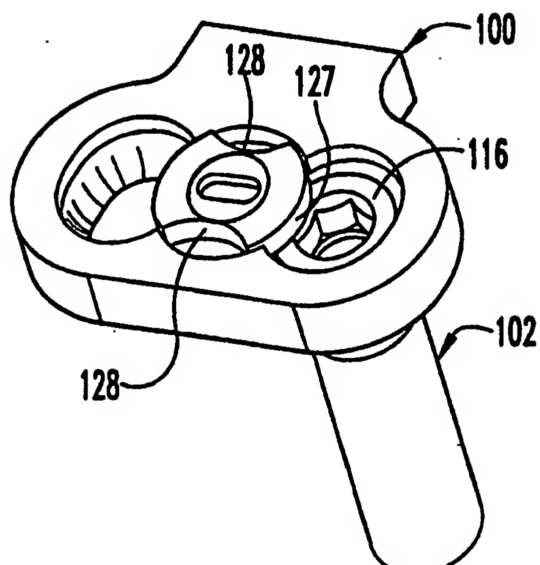

Fig. 22

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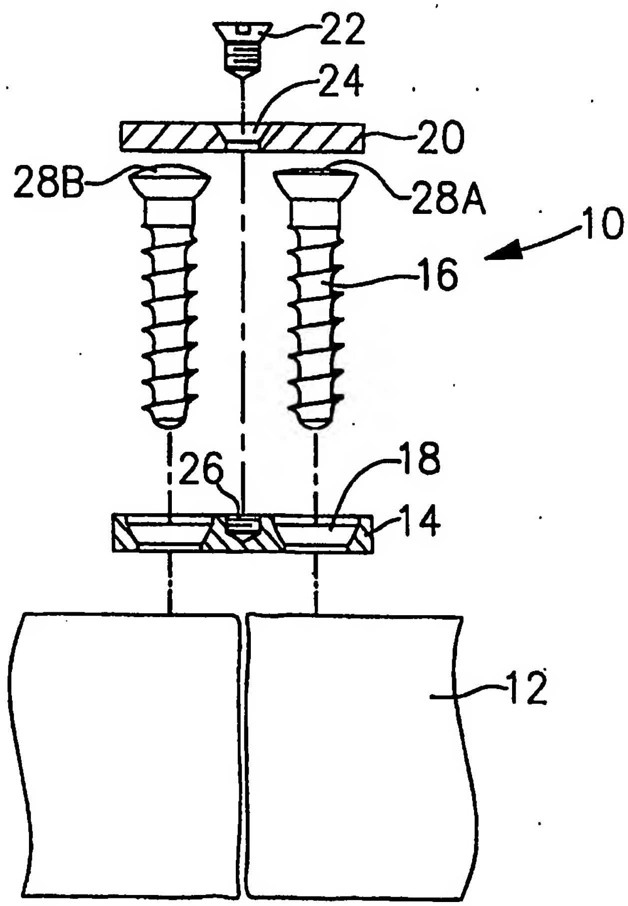
(54) Title: BONE PLATE AND BONE SCREW GUIDE MECHANISM

(57) Abstract

A bone plate (10) comprises a base plate (14) having at least two screw holes (18), and at least two bone screws (16) capable of securing the bone plate to a bone by insertion through the screw holes into the bone. The bone screws have heads (28) shaped to toggle within the screw holes. A retaining plate (20) is provided that is fixedly attachable to the base plate. The retaining plate covers at least a portion of each of the bone screws. The retaining plate, and base plate each contain set screw apertures (24, 26). A set screw (22) is provided to retain the retaining plate in place over the base plate by screwing the set screw through the set screw apertures in the retaining plate, and base plate. This design prevents the bone screw from backing out from the bone once screwed in through the base plate.



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BONE PLATE AND BONE SCREW GUIDE MECHANISM

FIELD OF THE INVENTION

The present invention is directed to a bone plate for assisting with the surgical arthrodesis (fusion) of two or more bones together, and a bone screw guide mechanism to assist in the proper drilling, tapping and placement of the bone screws to secure the plate.

BACKGROUND OF THE INVENTION

The spinal column of vertebrates provides support to bear weight and protection to the delicate spinal cord and spinal nerves. The spinal column comprises a series of vertebrae stacked on top of each other. There are typically seven cervical (neck), twelve thoracic (chest), and five lumbar (low back) segments. Each vertebra has a cylindrical shaped vertebral body in the anterior portion of the spine with an arch of bone to the posterior which covers the neural structures. Between each vertebral body is an intervertebral disk, a cartilaginous cushion to help absorb impact and dampen compressive forces on the spine. To the posterior the laminar arch covers the neural structures of the spinal cord and nerves for protection. At the junction of the arch and anterior vertebral body are articulations to allow movement of the spine.

Various types of problems can affect the structure and function of the spinal column. These can be based on degenerative conditions of the intervertebral disk or the articulating joints, traumatic disruption of the disk, bone or ligaments supporting the spine, tumor or infection. In addition congenital or acquired deformities can cause abnormal angulation or slippage of the spine. Slippage (spondylolisthesis) anterior of one vertebral body on another can cause compression of the spinal cord or nerves. Patients who suffer from one of more of these conditions often experience extreme and debilitating pain, and can sustain permanent neurologic damage if the conditions are not treated appropriately.

One technique of treating these disorders is known as surgical arthrodisis of the spine. This can be accomplished by removing the intervertebral disk and replacing it with bone and immobilizing the spine to allow the eventual fusion or growth of the bone across the disk space to connect the adjoining vertebral bodies together. The stabilization of the vertebra to allow fusion is often assisted by a surgically implanted device to hold the vertebral bodies in proper alignment and allow the bone to heal, much like placing a cast on a fractured bone. Such techniques have been effectively used to treat the above described conditions and in most cases are effective at reducing the patient's pain and preventing neurologic loss of function. However, there are disadvantages to the present stabilization devices and to the available tools to implant them.

The spinal fixation device needs to allow partial sharing of the weight of the vertebral bodies across the bone graft site. Bone will not heal if it is stress shielded from all weight bearing. The fixation device needs to allow for this weight sharing along with the micromotion that happens during weight sharing until the fusion is complete, often for a period of three to six months or longer, without breakage. The device must be strong enough to resist collapsing forces or abnormal angulation during the healing of the bone. Loss of alignment during the healing phase can cause a poor outcome for the patient. The device must be secure in its attachment to the spine to prevent migration of the implant or backout of the screws from the bone which could result in damage to the structures surrounding the spine, resulting in severe and potentially life threatening complications. The device must be safely and consistently implanted without damage to the patient.

Several types of anterior spinal fixation devises are in use currently. One technique involves placement of screws all the way through the vertebral body, called bicortical purchase. The screws are placed through a titanium plate but are not attached to the plate. This device is difficult to place, and overpenetration of the screws can result in damage to the spinal cord. The screws can back out of the plate into the surrounding tissues as they do not fix to the plate. Several newer generation devices have used a unicortical purchase of the bone, and in some fashion locking the screw to the plate to provide stability and secure the screw from backout. Problems have resulted from over ridged fixation and stress shielding, resulting in nonunion of the bony fusion, chronic micromotion during healing resulting in stress fracture of the fixation device at either the screw or the plate, insecure locking of the screw to the plate resulting in screw backout, or inadequate fixation strength and resultant collapse of the graft and angulation of the spine.

The conventional method for placing the bone screws entails drilling a hole, tapping the hole and threading the bone screw into the bone. To drill the hole a guide is held next to or attached to the plate. A drill is inserted into the guide and the hole drilled into the bone. The guide is removed and a tap is threaded through the hole attempting to follow the same angle as the drill hole. Caution must be used to prevent the sharp edges of the tap from damaging surrounding tissues or in creating too large a tap hole by toggling the handle of the tap. This will reduce the security of the screw bite into the bone and increases the likelihood of screw pullout. After tapping, the screw must be freehand guided at the proper angle into the hole created, inadvertent misalignment can reduce pullout strength or result in damage to surrounding nerves or arteries. Thus a need exists for a method of placing the screws that avoids these problems and risks to the patient.

SUMMARY OF THE INVENTION

The present invention is directed to a bone plate for stabilizing adjacent vertebrae or holding two portions of a bone together, e.g., a broken bone, while it heals. The bone plate comprises a base plate having at least two screw holes, at least two bone screws, and a bone screw locking means. The preferred bone screw locking means is a retaining plate. The bone plate is placed over at least two different bones or bone portions, and the bone screws are placed into each bone or bone portion through the bone screw holes in the base plate. The retaining plate is placed over the heads of the bone screws and fixedly attached to the base plate to prevent the bone screws from backing out of the bone. The bone screws have heads shaped to allow the bone screws to toggle within the screw holes in the base plate, preferably radiused heads. By controlling the amount of toggle, one can control the amount of weight borne by the bone plate.

The present bone plates are particularly useful for spinal fixation. For such a use, the base plate can be part of a larger device or structure. An example of such a device is a disk replacement spacer for stabilizing a portion of the spine. Such a device is described, for example, in U.S. Patent Application Serial No. 08/764,089, the disclosure of which is incorporated herein by reference.

The present bone plates also can be used anywhere in the body where anti-backout is important, i.e., where it is important to be sure that bone screws will not back out. It also is particularly useful anywhere in the body where partial weight bearing of bone graft is important. Such uses include, for example, small fragment bone sets from arm fractures, wrist fractures, ankle fractures, and hand fractures. The bone plate could also be used to secure hips in place, for femur fractures or the like.

The present invention is also directed to a bone screw guide mechanism for placing bone screws in the bones. The bone screw guide mechanism comprises a tubular member with open ends and a base fixedly attached at a predetermined angle to the tubular member at its bottom end. The base is mountable on the base plate of a bone plate so that the tubular member is generally coaxial with a bone screw hole in the base plate. Alternatively, the base can be mounted directly on the bone. Preferably, a handle is attached to the base or tubular member to provide ease of use. In a particularly preferred embodiment, an anchor screw is provided on the base of the bone screw guide mechanism to anchor the guide mechanism to the base plate during use.

The present invention is further directed to a method for inserting a bone screw into a bone through a base plate. A base plate having at least two bone screw holes is placed on a bone. The guide mechanism described above is placed on, and preferably mounted by means of a screw or the like, to the base plate so that the open bottom end of the tubular member is

in communication the bone screw hole in the base plate. A drill is inserted through the tubular member and, through the bone screw hole, and a hole is drilled in the bone. Similarly, a tap is inserted through the tubular member to tap, i.e., create threads in the hole. A bone screw is then screwed into the drilled and tapped hole through the bone screw hole of the base plate. The guide mechanism can then be removed Use of the inventive bone screw guide mechanism assures that the user will drill and tap the hole at virtually the identical angle, thereby avoiding inadvertent widening of the hole as occurs in current procedures.

DESCRIPTION OF THE DRAWINGS

These and other features and advantages of the present invention will be better understood by reference to the following detailed description when considered in conjunction with the accompanying drawings wherein:

FIG. 1 is a frontal view of a base plate according to the invention.

FIG. 2 is a side cross-sectional view of a bone screw locking mechanism according to the invention that is not assembled.

FIG. 3 is a side cross-sectional view of a bone screw locking mechanism according to the invention that is assembled.

FIG. 4 is a side cross-sectional view of a bone screw according to the invention illustrating the degree of toggle of the screw.

FIG. 5 is a side cross-sectional view of an alternative bone screw locking mechanism according to the invention where the retaining plate is situated in a recess in the base plate created by a raised structure on all four sides of the screw holes.

FIG. 6a is a projectional view of the bone plate of the embodiment of FIG. 5.

FIG. 6b is a projectional view of an alternative embodiment of the bone plate of FIG. 6a where the recess in the base plate is created by raised structures on only two sides of the screw holes.

FIG. 7 is a frontal view of another alternative bone screw locking mechanism according to the invention where the bone plate has six bone screw holes.

FIG. 8 is a side cross-sectional view of another embodiment of a bone screw locking mechanism according to the invention showing an alternative design for the bone screws and retaining plate.

FIG. 9 is a cross-sectional view of an embodiment of a bone screw guide mechanism of the invention having a single tubular member.

FIG. 10 is a cross-sectional view of an alternative embodiment of a bone screw guide mechanism of the invention having multiple tubular members.

FIG. 11 is a perspective view of an embodiment of a bone screw guide mechanism

according to the invention that has a handle.

FIG. 12 is a cross-sectional view of the bone screw guide mechanism of FIG. 11 across line 12-12.

FIG. 13 is a perspective view of a tapping tool for use in connection with the invention.

FIG. 14 is a perspective view of a screwdriver for use in connection with the invention.

DETAILED DESCRIPTION

A particularly preferred bone plate constructed in accordance with the present invention is shown in FIGs. 1 to 3. The bone plate **10** comprises a base plate **14**, at least two bone screws **16**, and at least one bone screw locking means.

The base plate **14** is a generally flat surface used to connect two or more bones **12**. As used herein, the term "bones" is intended to include both bones and bone fragments or portions. The base plate **14** can be of any suitable shape or size. In the illustrated embodiment, the base plate **14** is a generally rectangular plate. The base plate **14** can be any other suitable shape, such as an oval, square, circle, triangle, or kidney shape or a combination thereof. As discussed above, the base plate **14** can also be part of a larger device. The embodiment depicted in FIGs. 1 to 3, however, is an independent base plate, i.e., is not part of a larger device.

The base plate **14** can be made of any suitable material, and is preferably made of titanium or a titanium alloy. The base plate **14** is generally flat, but can be slightly curved to fit against the particular bones **12** being connected. The thickness of the base plate **14** is not critical. When the base plate is made of titanium or titanium alloy, a thickness of from about 0.5 mm to about 3 mm, and more preferably from about 1 mm to about 2 mm is preferred.

The base plate **14** contains at least two bone screw holes **18** for receiving the bone screws **16**. When the base plate **14** has only two bone screw holes **18**, they are situated far enough apart so that the bone screws **16** received by the screw holes **18** can screw into different bones **12**. In the illustrated embodiment, the base plate **14** also contains at least one set screw aperture **26** for receiving a set screw **22**. Preferably the set screw aperture **26** is located near the center of the base plate **14**.

The bone screws **16** can be made of any suitable material, and are preferably made of the same material as the base plate, which in the preferred embodiment is titanium or a titanium alloy. Each bone screws **16** has a head **28** that is capable of toggling within the screw hole **18**, as depicted in FIG. 4. Preferably the bone screws **16** have a radiused head. As used herein, the term "radiused head" means that the lower portion of the bone screw

head **28**, i.e. the portion that is nearest the shank, is generally rounded. The bone screws **16** could have any other suitable shape that permits toggling, for example, where the portion nearest the shank is generally diagonal.

As shown in FIG. 2, the top portion of each bone screw head **28** can be flat **28a**, slightly rounded **28b** or even hemispherical. The more rounded the top of the bone screw head **28**, the greater angle the bone screw **16** can toggle within the screw holes **18**. By controlling the maximum angle that the bone screws **16** can toggle within the screw hole, one can control, at least in part, the amount of weight borne by the base plate **14**.

Preferably the bone screw 16 can toggle within the screw hole **18** in at least two directions at an angle **30** of about 0 to about 20 or 30 degrees or more from normal depending on the circumstances. Still more preferably the bone screw **16** can toggle within the screw hole **18** in any direction at the above angles.

A bone screw locking means is any means for securedly covering at least one bone screw **16** so that the bone screw cannot back out from the bone **12** once screwed in through the base plate **14**. A preferred bone screw locking means comprises a retaining plate **20** and a retaining plate fixing means.

The retaining plate **20** is a generally flat or slightly curved plate that lies preferably flush against the bone plate **14**. The retaining plate **20** can be of any shape or size such that it covers at least a part of at least one bone screw **16**. More preferably the retaining plate **20** covers at least part of each bone screw **16** in an associated pair of bone screws **16**. However, multiple retaining plates **20** can be used to cover different bone screws **16**.

In the illustrated embodiment, the retaining plate **20** is a generally flat rectangular plate, similar to the base plate **14**. The retaining plate covers each bone screw **16** of an associated pair of bone screws. Preferably the retaining plate **20** covers 100 percent of the bone screw **16** or screws, but may cover less. Thus, when the retaining plate **20** is secured to the base plate **14**, the bone screws **16** cannot back out from the base plate **14**. The thickness of the retaining plate **20** preferably ranges from about 0.5 mm to about 2 mm, and more preferably from about 1 mm to about 1.5 mm.

The retaining plate **20** can be fixedly attached to the base plate **14** by any suitable retaining plate fixing means. In a preferred embodiment, the retaining plate **20** is attached to the base plate **14** with one or more set screws **22**. The set screw **22** is placed through a set screw hole **24** in the retaining plate **20**, inserted through the set screw aperture **26** in the base plate **14**, and tightened to secure the retaining plate **20** to the base plate **14**. The set screw can be made of any suitable material well known in the art, preferably titanium or a titanium alloy. In the preferred embodiment, the set screw is an hexagonal set screw that can be turned with an hexagonal driver. Other types of set screws can also be used.

An alternative embodiment of a bone plate according to the present invention is illustrated in FIGs. 5, 6a and 6b. The bone plate **14** comprises a recess **32** for receiving the retaining plate **20**. The recess **32** can be any shape or size. Preferably the recess **32** and retaining plate **20** are of a similar shape and size such that the retaining plate **20** fits snugly within the recess **32**. The recess **32** is defined by a raised structure **33** that forms a boundary around at least a portion of the retaining plate area. FIG. 6a depicts a recess **32** where the raised structure **33** surrounds all four sides of the retaining plate area. FIG. 6b depicts an alternative embodiment of a recess **32** where the raised structure **33** is situated on only two sides of the retaining plate area. Alternatively, the raised structure **33** can be situated on only one side of the retaining plate area, as shown, for example, in FIG. 7, discussed in more detail below.

The alternative embodiment depicted in FIG. 7 is particularly useful for fixation of three adjacent vertebrae. This design can be used in combination with a disk replacement spacer, such as that described in U.S. Patent Application Serial No. 08/764,089. In the embodiment shown, the base plate **14** contains three pairs of associated screw holes **18**. With this design, two bone screws **16** are screwed into each vertebra **12**. Between each adjacent screw holes **18** of a pair of screw holes is a set screw hole **26**. A separate retaining plate **20** covers each pair of adjacent screw holes **18**. In FIG. 7, the top pair of adjacent screw holes **18** is shown covered with a retaining plate **20**. In this embodiment, the base plate has raised ribs which extend adjacent **33** the long sides of each retaining plate **20**. The ribs **33** create a recess **32** for receiving the retaining plate **20**. This embodiment also contains spacer screw holes **36** for receiving spacer screws (not shown). The spacer screws allow the base plate **14** to be secured to a disk replacement spacer, such as that described in U.S. Patent Application Serial No. 08/764,089. The spacer screw holes **36** are situated between the pairs of adjacent screw holes **18**.

FIG. 8 shows an additional embodiment of a bone plate having an alternative design for the bone screws **16** and retaining plate **20**. Each bone screw head **28** contains a depression **34**, preferably a rounded depression. At the nadir of the depression **34** is an hexagonal socket or the like so that the screw can be turned by an hexagonally shaped driver, e.g., an Allen wrench. The retaining plate **20** contains protrusions **35**, preferably hemispherically-shaped protrusions, preferably with radially extending ribs that correspond generally in shape, size and number to depressions **34** and fit within the depressions **34** in the bone screw heads **28**. As in the embodiments described above, the bone screw head **28** is a radiused head such that the bone screw **16** can toggle within the screw hole **18**.

Another aspect of the present invention is a bone screw guide mechanism **38** for

putting in the bone screws **16**. As shown in FIG. 9, the guide mechanism **38** comprises a generally tubular member **40** fixedly attached to a base **42**. The top and bottom ends of the tubular member **40** are open.

The tubular member **40** is at a predetermined angle **44** to the base **42** which is the same angle as the desired angle of the screw holes in the bone. In practice, the base **42** of the guide mechanism **38** is placed flush on a base plate **14** such that the open end of the tubular member **40** is in communication with the bone screw hole **16** in the base plate **14**.

The user can insert a drill through the tubular member **40** to drill a hole in the bone **12** through the bone screw hole **16**. The user can then tap the hole in the bone without removing the guide mechanism **38** by inserting a tapping tool through the tubular member **40**. Once the hole is drilled and tapped, the guide mechanism **38** is removed and a bone screw **16** is inserted into the screw hole **18** in the base plate **14**.

The angle of the tubular member is selected based on the particular application. Preferably the tubular member **40** forms an angle **44** with the base **42** ranging from about 0 to about 20 or 30 degrees or more from normal, more preferably from about 0 to about 15 degrees from normal. The tubular member **40** can be made of any suitable material and is preferably made of titanium or stainless steel. The length and inner diameter of the tubular member will vary according to the application and the size of the bone screws involved. Tubular members **40** typically have an inner diameter ranging from about 2 mm to about 7 mm. The thickness of the tubular member is not critical.

The base **42** can be of any suitable shape, but is preferably generally rectangular. The base **42** may be generally flat or have any other cross-sectional shape that permits it to lie preferably flush against the base plate **14**. Like the tubular member, the thickness of the base is not critical. Thicknesses of about 1 mm to about 4 mm are preferred.

The tubular member **90** and base **42** are preferably a one piece unitary construction. However, two piece constructions in which the tubular member **40** is fixedly attachable or even removably attachable to the base may be used.

Multiple guide mechanisms **38** where the tubular members **40** form different angles with the base **42** can be packaged in the form of a kit.

In a preferred embodiment, as shown in FIG. 9, the base **42** contains a screw hole **46** for receiving a lock screw **48**. The lock screw **48** can be used to fixedly attach the base **42** to a base plate **14**. The lock screw **48** is inserted through the screw hole **46** in the base **42** and through the set screw aperture **26** in the base plate **14**.

In the embodiment shown in FIG. 9, the guide mechanism **38** comprises a single tubular member. An alternative embodiment is shown in FIG. 10. In this embodiment, the guide mechanism **38** comprises two elongated tubular members **40** fixedly attached to a

single base **42**. The base has a rectangular shape, but can have any shape similar to the base plate **14** with which it is to be used so that it can sit flush against the base plate. This base **42** design is particularly suitable for use with a base plate **14** as shown in FIG. 7, where each pair of adjacent bone screw holes **18** has two raised structures **33** on the longer sides of the rectangular section of the base plate **14** in which they are located. The base **42** can thus be placed into the recess **32** formed by the two raised structures **33**.

Any means for fixedly attaching or situating the base **42** on the base plate **14** can be used and are considered to be within the scope of the invention. If desired, the guide mechanism **38** may be designed to be mounted on the base plate **14** and held in place manually during drilling and tapping.

Another alternative embodiment of a bone screw guide mechanism **38** is depicted in FIGs. 11 and 12. Similar to the embodiments described above, the guide mechanism **38** comprises two generally tubular members **40** both fixedly attached to a base **42**. The top and bottom ends of each tubular member **40** are open. A handle **50** having proximal and distal end is anchored at its distal end to or near the base **42**. The handle **50** extends proximally away from the tubular members **40**. The proximal end of the handle **50** comprises a turnable knob **52**. The knob **52** is attached to a cable **54** having proximal and distal ends that extends within the handle **50**. The distal end of the cable **54** is attached to a threaded anchoring screw **56** that extends distally from the base **42**. Turning the knob **52** turns the cable **54**, which, in turn, turns the anchoring screw **56**.

In preferred practice, a base plate **14** is placed directly on the bone into which the screws are to be inserted, and the guide mechanism **38** is placed over the base plate **14**. The anchoring screw **56** is used to hold the bone screw guide mechanism **38** in place against the base plate **14** by screwing the anchoring screw **56** into set screw aperture **26** of the base plate **14** until the face of the base **42** of the guide mechanism **38** is flush against the base plate **14**. A drilling tool having an elongated stem is inserted through each tubular member **40** to drill holes in the bone. If desired before drilling, a tack tool, a tool having an elongated stem and a removable sharp tack at its distal end, may be inserted through each tubular member and pushed distally so that the tack creates a starter hole in the bone to facilitate drilling. After drilling, a tapping tool is inserted through each tubular member to tap the drilled holes. The stems of the tack tool, drilling tool and tapping tool have generally the same diameter which is slightly less than the inner diameter of the tubular members **40** of the guide mechanism of such that the stems of the tools may be slidably received in the tubular members but are afforded no or almost no lateral "play." Following tapping, bone screws **16** are screwed into the drilled and tapped holes through the bone screw holes **18** in the base plate **14**.

The angle of the face of base **42** of the guide mechanism **38** determines the angle at which the bone screws **16** will be secured in the bone. For example, when the face of the guide mechanism base **42** is normal, i.e., 90° to the axis of the tubular members **40**, the holes drilled and tapped into the bone will be normal to the base plate **14** and to the face of the bone. Such a guide mechanism is referred to herein as an 0° guide. If the face of the base **42** of the guide mechanism **38** is at a selected angle other than 90° from the axis of the tubular members **40**, then the holes drilled and tapped into the bone will be at an angle other than normal to the base plate and face of the bone. A guide mechanism **38** which provides for the drilling and tapping of holes at an angle 15° above that created by an 0° guide is referred to herein as a 15° guide and so on.

The proximal end of each tubular member **40** of the guide mechanism **38** comprises a protrusion **58**. This feature is beneficial when the bone screw guide mechanism **38** is used with the tapping tool **60** depicted in FIG. 13. The tapping tool **60** comprises a handle **62**, a stem **64**, and a threaded tap **66**. Mounted on the stem **64** is an adjustable depth guide **68**. The depth guide **68** comprises a slidable housing **70** and a spring loaded pin **72**. When pressure is exerted on the pin **72**, the slidable housing **70** can be slid between two or more positions along the length of the stem **64**. The position of the depth guide **68** on the stem **64** dictates the depth that the tap **66** and stem **64** can be inserted into the tubular member **40** of the guide mechanism **38**. The housing **70** comprises protrusions **72** at its distal end. As the tapping tool **60** is rotated within the tubular member **40** of the guide mechanism **38** and reaches the depth dictated by the depth guide 68, one of the protrusions **72** on the depth guide housing will engage protrusion **58** on the tubular member **40** of the guide mechanism, preventing further rotation of the tapping tool **60**. This mechanism prevents stripping of the tapped hole in the bone that would result from further rotation of the tapping tool **60**.

The depth guide **38** described above is also useful for the drilling tool. However, for a drilling tool, it is unnecessary to include protrusions on the depth guide housing.

An additional tool useful in connection with the present invention, a screwdriver, is depicted in FIG. 14. The screwdriver **74** comprises a handle **76**, a stem **78**, and a head **80**. The head **80** comprises two rounded protrusions **82**, generally on opposite sides of the head. The protrusions **82** fit into corresponding holes **84** provided in the head of a screw, for example, as shown in FIG. 7. It is understood that the number and shape of the protrusion, **82** may vary as desired. For example, a single axial hexagonal protrusion may be used in conjunction with screws having a corresponding axial hexagonal hole in the screw head.

Further, it is understood that, if desired, the guide mechanism of the type described

above may comprise only a single tubular member along with a handle. Means may or may not be provided for anchoring the guide mechanism to a base plate 14. Consequently, a guide mechanism used entirely free hand is contemplated by and within the scope of this invention.

It is presently preferred to provide a kit having base plates of differing sizes, bone screws of differing lengths and locking plates complementary to the base plates. The kit may further comprise one or more guide mechanisms, preferably at least an 0° guide and a 15° guide, a tack tool, a drilling tool, tapping tool and/or one or more screw driving tools.

While embodiments and applications of this invention have been shown and described, it would be apparent to those skilled in the art that many more modifications are possible without departing from the inventive concepts herein. The invention, therefore, is not to be restricted except in the spirit of the appended claims.

CLAIMS:

1. A bone plate comprising:

a base plate having at least two screw holes;

at least two bone screws capable of securing the bone plate to a bone by insertion through the screw holes into the bone, wherein the bone screws have heads shaped to toggle withing the screw holes;

a bone screw locking means capable of securedly covering at least one bone screw so that the bone screw cannot back out from the bone once screwed in through the base plate.

2. A bone plate according to claim 1, wherein the bone screw locking means comprises:

a retaining plate fixedly attachable to the base plate, wherein the retaining plate covers at least a portion of each of the bone screws, and

a retaining plate fixing means for fixedly attaching the retaining plate to the base plate.

3. A bone plate according to claim 2, wherein the fixing means comprises a set screw and wherein the base plate also has a set screw aperture.

4. A bone plate according to claim 2, wherein the retaining plate covers 100 percent of at least one bone screw.

5. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in at least two directions at an angle of about 0 to about 20 degrees from normal.

6. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in at least two directions at an angle of about 0 to about 15 degrees from normal.

7. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 degrees to about 20 degrees from normal.

8. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 to about 15 degrees from normal.

9. A bone plate according to claim 1, wherein each bone screw has a radiused head.

10. A bone plate according to claim 2, wherein each bone screw head contains a depression and wherein the retaining plate contains protrusions that correspond in shape, size and number to and that are capable of fitting within the depressions in the bone screw heads.

11. A bone plate according to claim 10, wherein each bone screw has a radiused head.

12. A bone plate according to claim 1, wherein the base plate comprises at least two pairs of adjacent screw holes.

13. A bone plate according to claim 1, wherein the base plate is made of titanium or a titanium alloy.

14. A bone plate comprising

a base plate having two screw holes and a set screw hole between the screw holes;

two bone screws capable of securing the bone plate to a bone by insertion through the screw holes into the bone;

a retaining plate fixedly attachable to the base plate, wherein the retaining plate has a size sufficient to cover the bone screws and a set screw aperture extending therethrough so that the set screw aperture is aligned with the set screw hole in the base plate when the retaining plate is placed on the base plate;

a set screw for fixedly attaching the retaining plate to the base plate by extending through the set screw aperture in the retaining plate and into the set screw hole in the base plate.

15. A bone plate according to claim 14, wherein each bone screw has a radiused head.

16. A bone plate according to claim 14, wherein each bone screw head contains a depression and wherein the retaining plate contains protrusions that correspond in shape, size and number to and that are capable of fitting within the depressions in the bone screw heads.

17. A bone plate according to claim 16, wherein each bone screw has a radiused head.

18. A bone plate according to claim 14, wherein each bone screw can toggle within the corresponding screw hole in at least two directions at an angle of about 0 to about 20 degrees from normal.

19. A bone plate according to claim 14, wherein each bone screw can toggle within the corresponding screw hole in at least two directions at an angle of about 0 to about 15 degrees from normal.

20. A bone plate according to claim 14, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 to about 20 degrees from normal.

21. A bone plate according to claim 14, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 to about 15 degrees from normal.

22. A bone plate according to claim 14, wherein the base plate and retaining plate are both made of titanium or a titanium alloy.

23. A bone screw guide mechanism for putting a bone screw into a bone through a base plate, comprising:

a generally tubular member having an open top end, an open bottom end, and an interior region having a diameter capable of receiving a drilling tool, and

a base fixedly attached to the tubular member at its bottom end.

24. A bone screw guide mechanism according to claim 23, wherein the tubular member forms an angle with the base ranging from about 0 to about 20 degrees from normal.

25. A bone screw guide mechanism according to claim 23, wherein the tubular member forms an angle with the base ranging from about 0 to about 15 degrees from normal.

26. A bone screw guide mechanism according to claim 23, further comprising a handle extending proximally from the base to permit the user to hold the base against the bone.

27. A bone screw guide mechanism according to claim 23, further comprising an anchoring screw attached to the base and a means for turning the anchoring screw, whereby the anchoring screw is capable of anchoring the base to the base plate.

28. A bone screw guide mechanism according to claim 23, wherein the mechanism further comprises a second tubular member having an open top end and an open bottom end, wherein the second member is fixedly attached near its bottom end to the base.

29. A kit comprising a plurality of guide mechanisms according to claim 23.

30. A method for inserting a bone screw into a bone through a base plate comprising:

providing a bone screw guide mechanism comprising:

a tubular member having an open top end and an open bottom end and

a base fixedly attached to the tubular member at its bottom end;

placing a base plate comprising at least one screw hole on the bone;

placing the base of the bone screw mechanism on the base plage;

inserting a drill through the tubular member and through the screw hole in the base plate, and drilling a hole in the bone;

inserting a tap through the tubular member and through the screw hole in the base plate, and tapping the drilled hole; and

inserting a bone screw through the tubular member, through the bone screw hole and into the drilled and tapped hole.

31. A method according to claim 30, wherein the tubular member forms an angle with the base ranging from about 0 to about 20 degrees from normal.

32. A method according to claim 30, wherein the tubular member forms an angle with the base ranging from about 0 to about 15 degrees from normal.

33. A method according to claim 30, further comprising the step of anchoring the base of the guide mechanism to the base plate.

AMENDED CLAIMS

[received by the International Bureau on 12.March.1999.(12.03.99); original claims 1, 5-8, 14, 18-21, 23, 26, 27, 30 and 33 amended; remaining claims unchanged (5 pages)]

1. A bone plate comprising:

a base plate having at least two screw holes;

at least two bone screws capable of securing the bone plate to a bone by insertion through the screw holes into the bone; and

a bone screw locking means capable of securedly covering at least one bone screw so that the bone screw cannot back out from the bone once screwed in through the base plate; wherein each bone screw has a head shaped to toggle withing its corresponding screw hole when the bone screw locking means covers that screw.

2. A bone plate according to claim 1, wherein the bone screw locking means comprises:

a retaining plate fixedly attachable to the base plate, wherein the retaining plate covers at least a portion of each of the bone screws, and

a retaining plate fixing means for fixedly attaching the retaining plate to the base plate.

3. A bone plate according to claim 2, wherein the fixing means comprises a set screw and wherein the base plate also has a set screw aperture.

4. A bone plate according to claim 2, wherein the retaining plate covers 100 percent of at least one bone screw.

5. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in at least two directions at an angle of about 0 to about 20 degrees from normal when the bone screw locking means covers that screw.

6. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in at least two directions at an angle of about 0 to about 15 degrees from normal when the bone screw locking means covers that screw.

7. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 degrees to about 20 degrees from normal when the bone screw locking means covers that screw.

8. A bone plate according to claim 1, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 to about 15 degrees from normal when the bone screw locking means covers that screw.

9. A bone plate according to claim 1, wherein each bone screw has a radiused head.

10. A bone plate according to claim 2, wherein each bone screw head contains a depression and wherein the retaining plate contains protrusions that correspond in shape, size and number to and that are capable of fitting within the depressions in the bone screw heads.

11. A bone plate according to claim 10, wherein each bone screw has a radiused head.

12. A bone plate according to claim 1, wherein the base plate comprises at least two pairs of adjacent screw holes.

13. A bone plate according to claim 1, wherein the base plate is made of titanium or a titanium alloy.

14. A bone plate comprising

a base plate having two screw holes and a set screw hole between the screw holes;

two bone screws capable of securing the bone plate to a bone by insertion through the screw holes into the bone;

a retaining plate fixedly attachable to the base plate, wherein the retaining plate has a size sufficient to cover the bone screws and a set screw aperture extending therethrough so that the set screw aperture is aligned with the set screw hole in the base plate when the retaining plate is placed on the base plate;

a set screw for fixedly attaching the retaining plate to the base plate by extending through the set screw aperture in the retaining plate and into the set screw hole in the base plate;

wherein each bone screw has a head shaped to toggle withing its corresponding screw hole when the retaining plate covers that screw.

15. A bone plate according to claim 14, wherein each bone screw has a radiused head.

16. A bone plate according to claim 14, wherein each bone screw head contains a depression and wherein the retaining plate contains protrusions that correspond in shape, size and number to and that are capable of fitting within the depressions in the bone screw heads.

17. A bone plate according to claim 16, wherein each bone screw has a radiused head.

18. A bone plate according to claim 14, wherein each bone screw can toggle within the

corresponding screw hole in at least two directions at an angle of about 0 to about 20 degrees from normal when the retaining plate covers that screw.

19. A bone plate according to claim 14, wherein each bone screw can toggle within the corresponding screw hole in at least two directions at an angle of about 0 to about 15 degrees from normal when the retaining plate covers that screw.

20. A bone plate according to claim 14, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 to about 20 degrees from normal when the retaining plate covers that screw.

21. A bone plate according to claim 14, wherein each bone screw can toggle within the corresponding screw hole in any direction at an angle of about 0 to about 15 degrees from normal when the retaining plate covers that screw.

22. A bone plate according to claim 14, wherein the base plate and retaining plate are both made of titanium or a titanium alloy.

23. A unitary bone screw guide mechanism for putting a bone screw into a bone through a base plate, comprising:

a generally tubular member having an open top end, an open bottom end, and an interior region having a diameter capable of receiving a drilling tool,

a base fixedly attached to the tubular member at its bottom end,

an anchoring screw attached to the base, and

a means for turning the anchoring screw, whereby the anchoring screw is capable of anchoring the base to the base plate.

24. A bone screw guide mechanism according to claim 23, wherein the tubular member forms an angle with the base ranging from about 0 to about 20 degrees from normal.

25. A bone screw guide mechanism according to claim 23, wherein the tubular member forms an angle with the base ranging from about 0 to about 15 degrees from normal.

26. A bone screw guide mechanism according to claim 23, further comprising a handle having proximal and distal ends and extending proximally from the base to permit the user to hold the base against the bone.

27. A bone screw guide mechanism according to claim 26, wherein the means for turning the anchoring screw comprises:

a turnable knob near the proximal end of the handle; and

a cable extending from the turnable knob and through the handle and connected to the anchoring screw;

whereby rotational movement of the turnable knob results in rotational movement of the cable and anchoring screw.

28. A bone screw guide mechanism according to claim 23, wherein the mechanism further comprises a second tubular member having an open top end and an open bottom end, wherein the second member is fixedly attached near its bottom end to the base.

29. A kit comprising a plurality of guide mechanisms according to claim 23.

30. A method for inserting a bone screw into a bone through a base plate comprising: providing a unitary bone screw guide mechanism comprising:

a tubular member having an open top end and an open bottom end;

a base fixedly attached to the tubular member at its bottom end;

an anchoring screw attached to the base, and

a means for turning the anchoring screw;

placing a base plate comprising at least one screw hole on the bone;

placing the base of the bone screw mechanism on the base plate;

anchoring the base to the base plate with the anchoring screw;

inserting a drill through the tubular member and through the screw hole in the base plate, and drilling a hole in the bone;

inserting a tap through the tubular member and through the screw hole in the base plate, and tapping the drilled hole; and

inserting a bone screw through the tubular member, through the bone screw hole and into the drilled and tapped hole.

31. A method according to claim 30, wherein the tubular member forms an angle with the base ranging from about 0 to about 20 degrees from normal.

32. A method according to claim 30, wherein the tubular member forms an angle with the base ranging from about 0 to about 15 degrees from normal.

33. A method according to claim 30, wherein the means for turning the anchoring

screw comprises:

a turnable knob near the proximal end of the handle; and

a cable extending from the turnable knob and through the handle and connected to the anchoring screw;

whereby rotational movement of the turnable knob results in rotational movement of the cable and anchoring screw.

FIG. 1

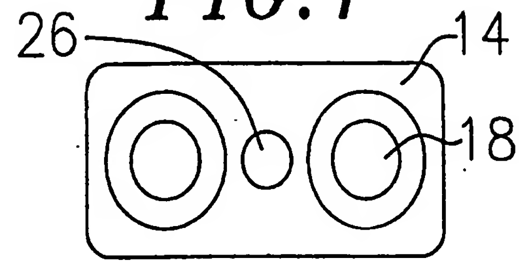


FIG. 2

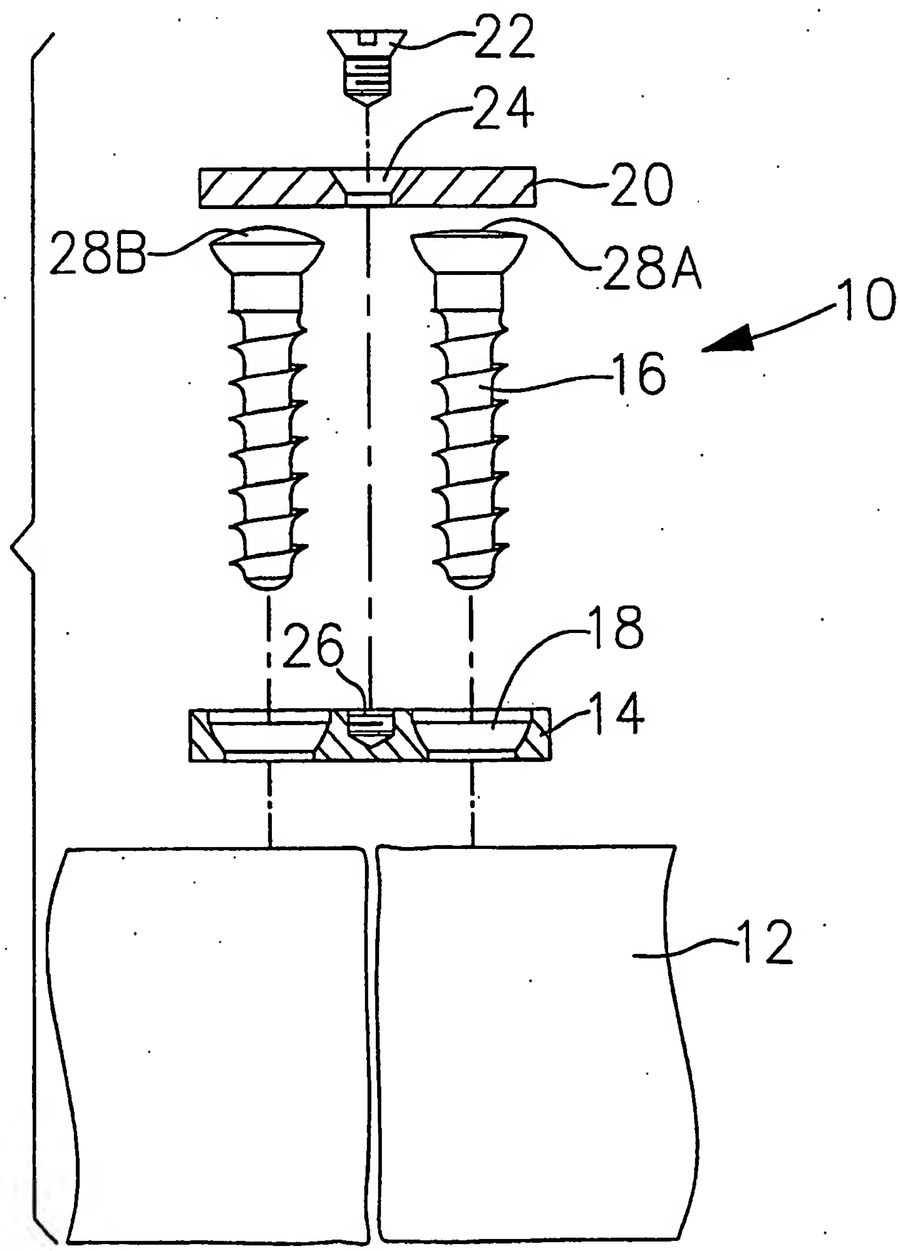


FIG.3

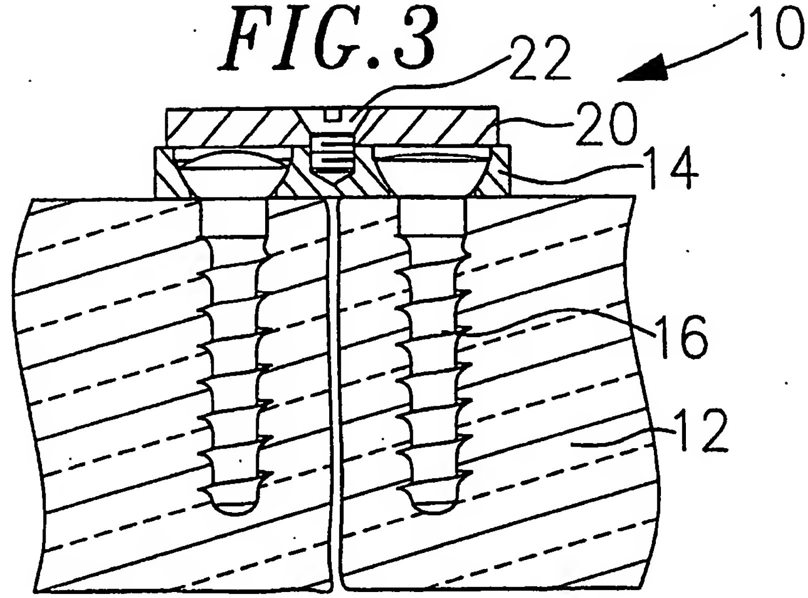


FIG.4

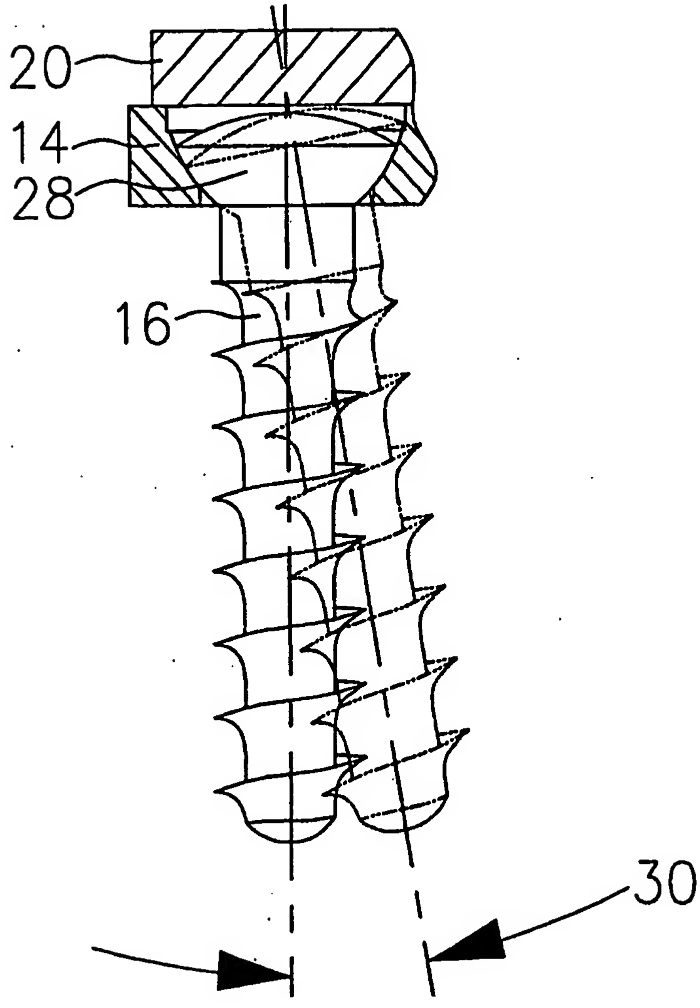


FIG.5

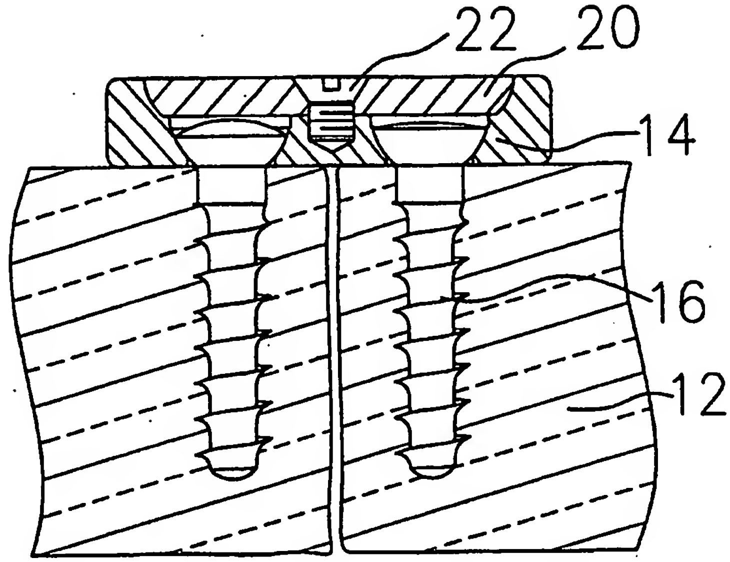


FIG.6A

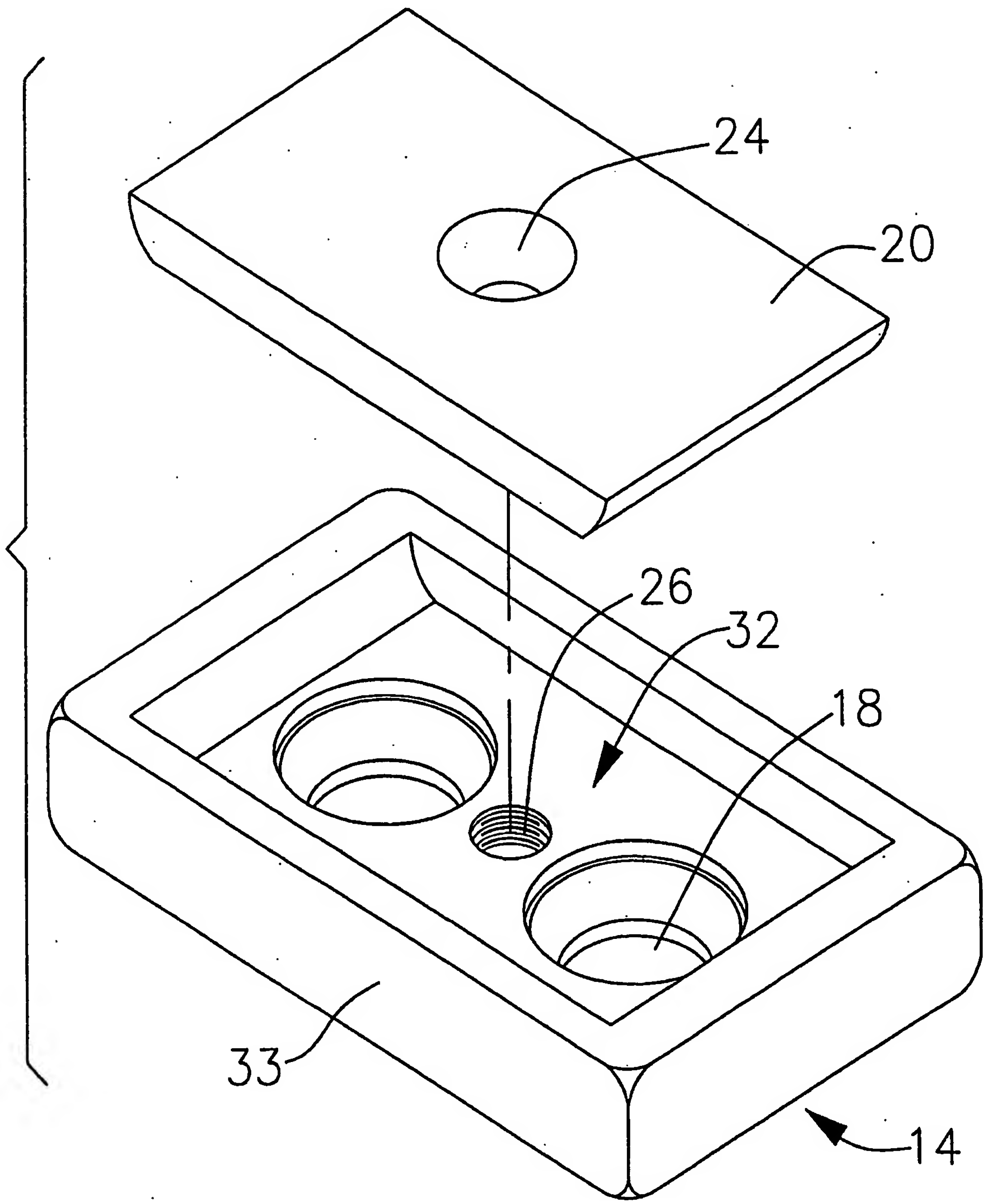


FIG.6B

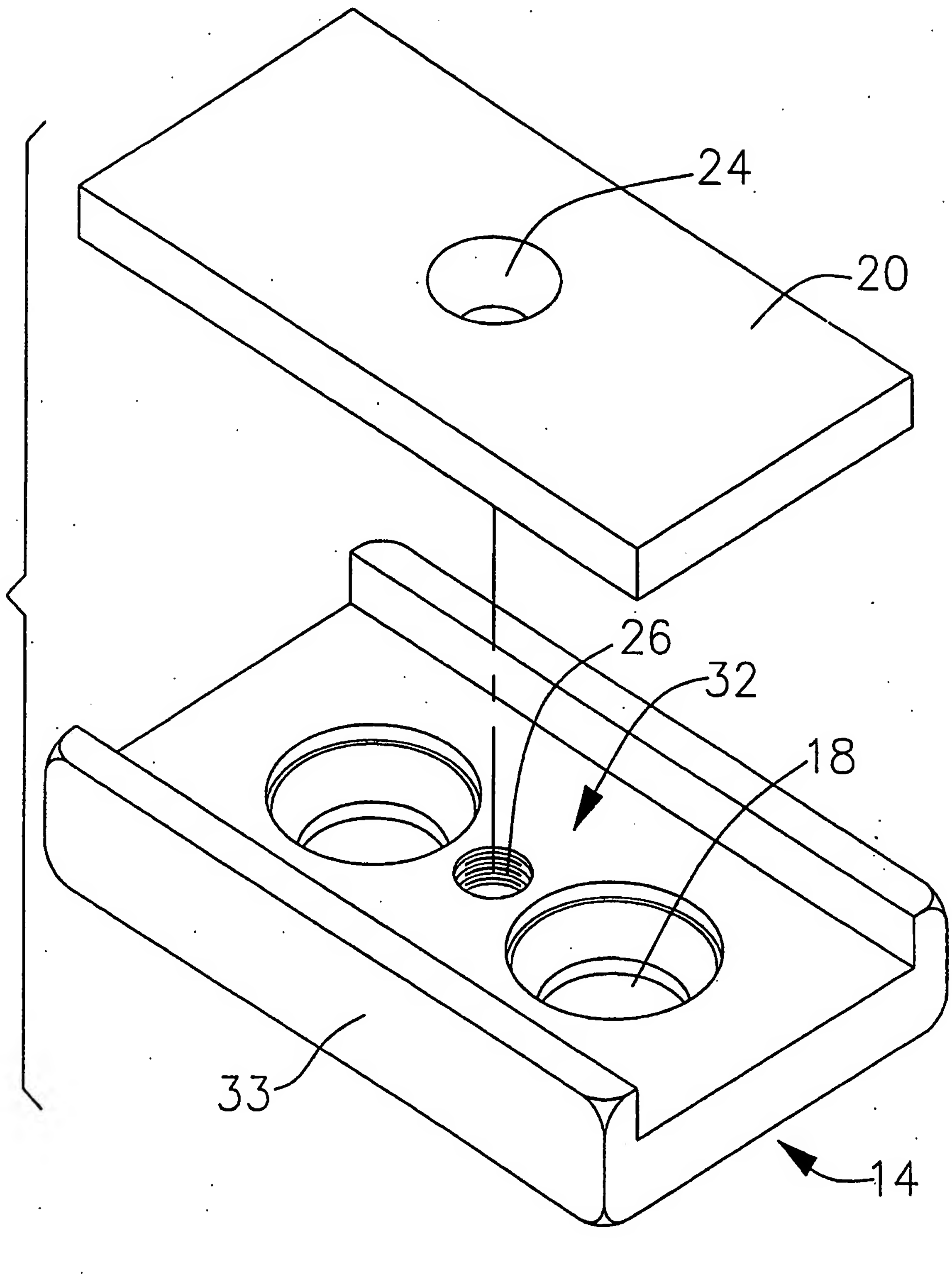


FIG.7

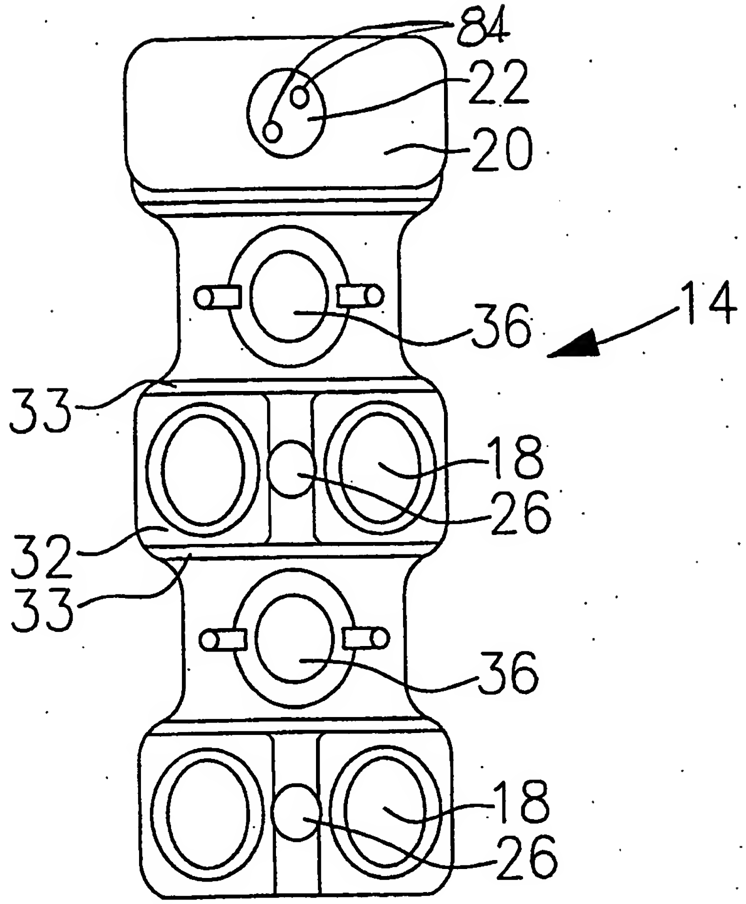


FIG.8

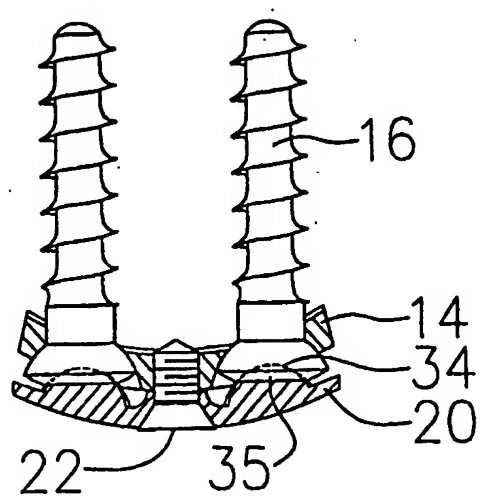


FIG. 9

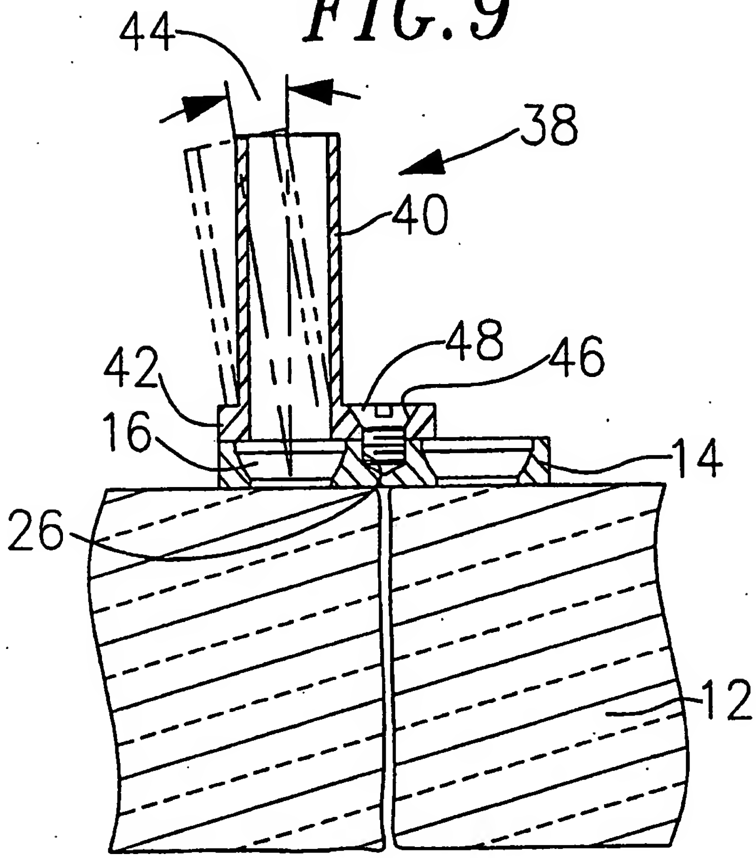
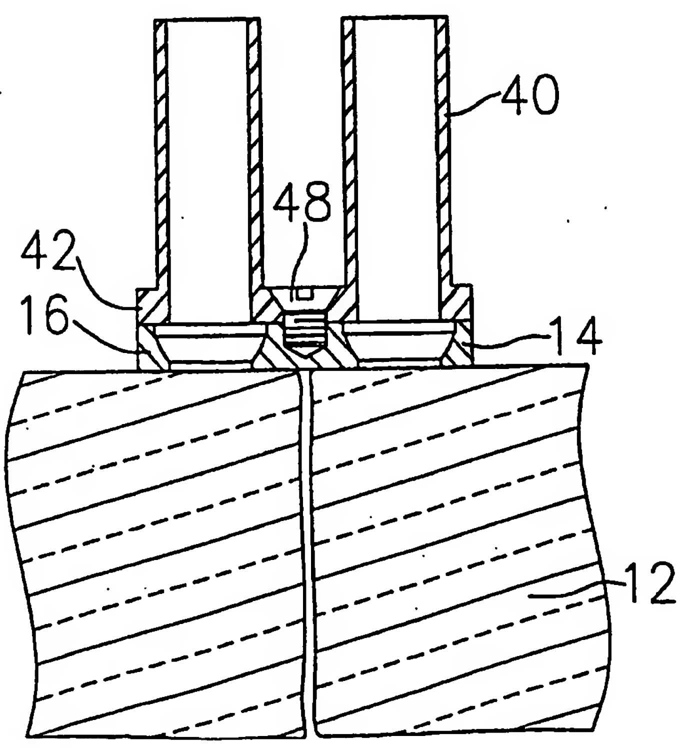


FIG. 10



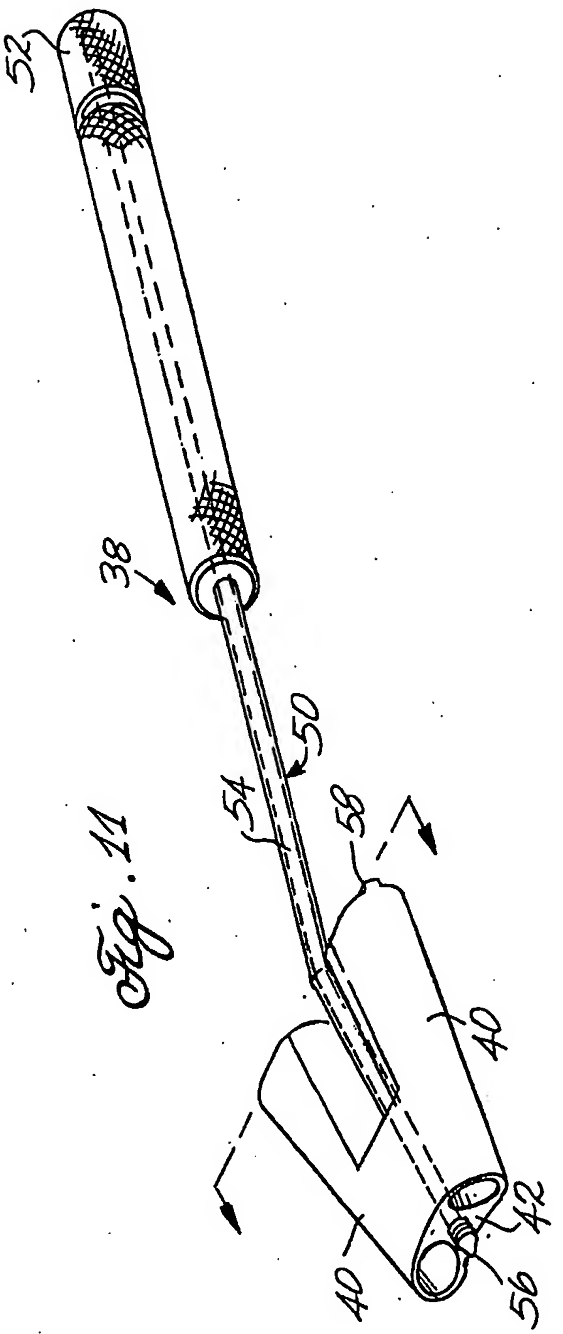


Fig. 11

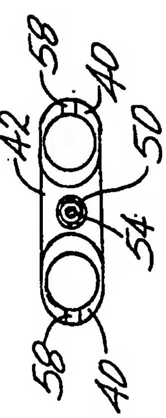


Fig. 12

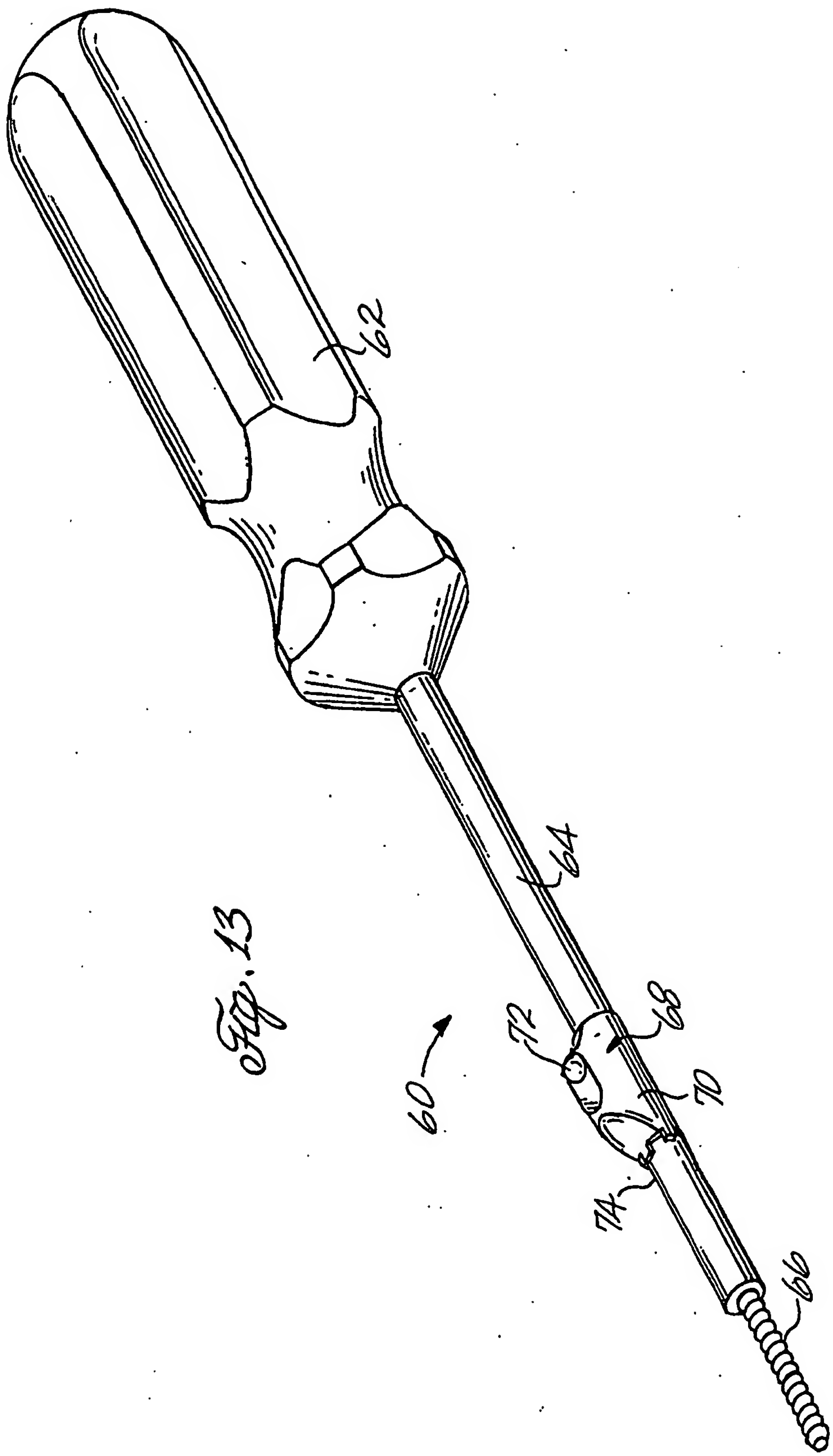
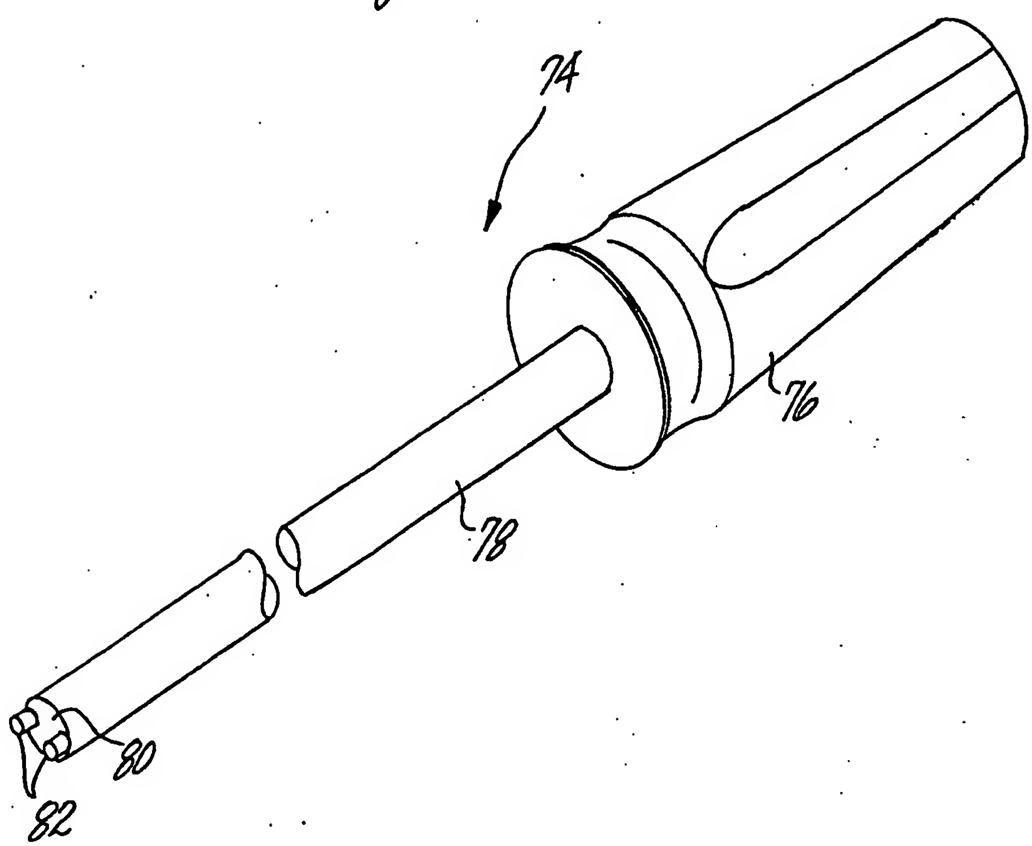


Fig. 13

Fig. 14



A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/80
US CL :606/71

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/60, 61, 69-73, 96, 104

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 4,794,918 A (WOLTER) 03 January 1989, Figs. 1-13.	1-12, 14-21 --- 13, 22
X	US 5,423,826 A (COATES et al.) 13 June 1995, Figs. 10-20, and col. 10, line 36 through col. 12, line 66.	23-33

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

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Date of the actual completion of the international search	Date of mailing of the international search report
18 DECEMBER 1998	14 JAN 1999
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